IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JAMES T. O'NEILL,

Plaintiff,

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION

Defendants.

Case No.:

06CV2498
JUDGE MANNING
MAGISTRATE DENLOW

FILED
MAY - 4 2006
MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

COMPLAINT FOR INJUNCTIVE RELIEF

I. Introduction.

1. In response to a series of Freedom of Information Act (FOIA) requests submitted by Plaintiff, the Centers for Medicare and Medicaid Services (CMS) has responded with letters that promise only to address the requests eventually. CMS has produced nothing in the way of agency records or of decisions whether to release records. Further, CMS simply has ignored Plaintiff's administrative appeal regarding one FOIA request. The FOIA, and the HHS regulations that are applicable to CMS – and are more stringent than the FOIA itself – demand more of CMS than the agency has delivered.

2. This action brings claims under the FOIA, 5 U.S.C. § 552, as amended, and the FOIA implementing regulations of the Department of Health and Human

Services ("HHS"), 45 C.F.R. §§ 5.1 – 5.69, as well as the Administrative Procedure Act (APA), 5. U.S.C. §§ 701-706.

3. Plaintiff seeks relief in the form of an Order compelling CMS's production of records concerning (a) a public notice-and-comment rulemaking by CMS, and (b) several aspects of CMS's own FOIA policies.

4. Plaintiff also requests judicial compulsion for the production of records regarding public actions of an insurance carrier, Wisconsin Physicians Service Insurance Corporation (WPS), which serves as an instrument of CMS in the administration of Medicare Part B. Defendants' handling of FOIA requests regarding WPS seems by design to ensure that the FOIA deadlines cannot be met. WPS apparently possesses responsive records, but disclaims authority to release them. CMS has the authority to release records, but appears to employ a circuitous process to obtain documents related to WPS. When CMS says "talk to WPS," WPS says "talk to CMS's Chicago office," and CMS's Chicago office says "talk to CMS's Baltimore office," something is wrong. The buckslip has to stop somewhere.

II. Jurisdiction and Venue.

5. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. § 552 (a)(4)(B) and 552 (a)(6)(E)(iii). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701-706.

6. Venue in this Court is proper under 5 U.S.C. § 552(a)(4)(B).

III. Parties.

A. Plaintiff.

7. Plaintiff is a resident of the State of Illinois, and the person who submitted to CMS and WPS the FOIA requests at issue in this matter.

B. Defendants CMS and HHS.

8. Defendant CMS is a unit of the U.S. Department of Health and Human Services. Defendant HHS is a cabinet-level federal agency. Both HHS and CMS are agencies within the meaning of 5 U.S.C. § 552(f).

9. CMS formerly was named the Health Care Financing Administration (HCFA). HHS announced in June 2001 that HCFA had changed its name to CMS. For all purposes relevant to this Complaint, CMS is the same agency as the former HCFA. In this Complaint, Plaintiff refers to both agencies under the blanket title CMS.

C. Defendant WPS.

(1) Background: How Private Insurance Carriers Such as WPS Fit Into the Medicare Part B Scheme.

10. Title XVIII of the Social Security Act, as amended, 42 U.S.C. §§ 1395 – 1395hhh, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare Program. The Secretary of HHS administers the Medicare Program through CMS, a component of HHS.

11. The Medicare program is comprised of several parts, only one of which it at issue in this case. Medicare Part B provides federal government funds to help pay for, among other things, laboratory procedures performed for Medicare beneficiaries.

12. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. Eligible individuals

who are 65 years of age or older, or disabled, may enroll in Part B to obtain benefits in return for payments of monthly premiums established by HHS. However, payments under the Medicare Program often are made directly to service providers rather than to the patient ("the beneficiary"). This occurs when the provider accepts assignment of the right to payment from the beneficiary. In that case, the provider submits the bill directly to Medicare for payment.

13. The United States provides reimbursement for Medicare claims through CMS. CMS, in turn, contracts with private insurance carriers to administer, process, and pay Part B claims from the Federal Supplementary Medical Insurance Trust Fund (the Part B Trust Fund). In this capacity, the carriers act on behalf of CMS.

14. Medicare Part B carriers exercise governmental authority delegated to them by CMS, pursuant to law.

15. The United States Government's position with regard to Medicare Part B carriers is that the carriers enjoy sovereign immunity when they engage in activities related to the administration of Medicare Part B, because the carriers perform governmental functions and exercise delegated authority in implementing statutory provisions.

(2) Defendant WPS.

16. Defendant WPS is an insurance company with its primary place of business in Monona, Wisconsin.

17. WPS exercises governmental authority delegated to it by CMS, pursuant to law and via contract, as the Medicare Part B carrier for the states of Illinois, Wisconsin, Michigan, and Minnesota. WPS holds itself out as an agency to which the

public may submit FOIA requests, and responds to those requests on letterhead indicating that the responses come from "Medicare Part B."

18. The United States Government's position with regard to WPS is that WPS enjoys sovereign immunity when it engages in activities related to the administration of Medicare Part B, because WPS performs governmental functions and exercises delegated authority in implementing statutory provisions.

19. For purposes of its administration of Medicare Part B and of the governmental records at issue in this Complaint, WPS is an "agency" within the meaning of 5 U.S.C. §§ 551(1) and 552(f)(1).

IV. Plaintiff's FOIA Requests Regarding a CMS Rulemaking, CMS's Constructive Denial of those Requests, and the Demonstrated Futility of Plaintiff's Administrative Appeal.

A. Background – The CMS Rulemaking

20. On Aug. 15, 2003, CMS published in the *Federal Register* a Notice of Proposed Rulemaking ("Proposed Rule") entitled "Medicare Programs; Revisions to Payment Policies Under the Physicians Fee Schedule for the Year 2004." The Proposed Rule appeared in the *Federal Register* for Aug. 15, 2003, beginning at page 49,030 of the daily edition.

21. The preamble to the Proposed Rule discussed Medicare reimbursement for flow cytometry (pp. 49,047-49,048), and included a reference (p. 49,048, col. 1) to a "review of flow cytometry reports" by CMS.

22. On November 7, 2003, CMS published in the *Federal Register* a Final Rule on the subjects of the Proposed Rule. The Final Rule was entitled "Medicare Programs; Revisions to Payment Policies Under the Physicians Fee Schedule for the Year

2004." The Final Rule appeared in the November 7, 2003 *Federal Register*, beginning at page 63,196 of the daily edition of the *Federal Register*.

23. The preamble to the Final Rule made reference to public comments received, in response to the Proposed Rule, regarding flow cytometry issues (p. 63,216).

B. Plaintiff's August 2005 FOIA Requests Regarding the CMS Rulemaking, and CMS's Dilatory Responses.

24. Plaintiff submitted two FOIA requests to CMS regarding the subject matter of the Proposed Rule and the Final Rule. Both of the requests were dated August 29, 2005. Plaintiff sent these requests to CMS on August 30, 2005 via United States Postal Service Priority Mail.

25. The two one-page documents included with this Complaint as **Exhibit 1** are true and correct copies (save for the copies' absence of Plaintiff's signature) of Plaintiff's two Aug. 29, 2005 FOIA requests to CMS.

26. CMS received Plaintiff's August 29, 2005 FOIA requests on Sept. 6, 2005.

27. In two letters dated September 9, 2005, CMS responded to Plaintiff's August 29, 2005 FOIA requests.

28. Other than differences in the reference numbers, the two letters sent by CMS to Plaintiff in response to Plaintiff's August 2005 FOIA requests were identical form letters. These letters reflect CMS's standard form letter for responding to FOIA requests.

29. **Exhibit 2** to this Complaint consists of true and correct copies of two documents: the CMS response letter regarding the Plaintiff's FOIA request assigned

CMS reference number C05FOI12250 (DJH), and the CMS response letter regarding the Plaintiff's FOIA request assigned CMS reference number C05FOI12251 (DJH).

30. The CMS response letters to Plaintiff did not set forth any determination as to whether CMS would release the requested records. Instead, the letters purported to invoke an alleged "policy" of "first in, first out" case processing.

31. Plaintiff attempted to obtain more information from CMS by telephoning Ms. Jones-Holman, as the CMS letters suggested. In a telephone conversation on October 27, 2005, Ms. Jones-Holman was unwilling or unable to provide any information as to when responses to Plaintiff's FOIA requests might be forthcoming.

32. In the October 27, 2005 telephone conversation, Ms. Jones-Holman informed Plaintiff, and Plaintiff therefore alleges, that the CMS FOIA office forwarded Plaintiff's August 2005 FOIA requests to the CMS "Program Office" on Sept. 9, 2005. Plaintiff requested contact information for the Program Office so that he could pursue his inquiry into the status of the FOIA requests, but Ms. Jones-Holman refused to provide this information.

33. Plaintiff has received no further communication from CMS regarding his CMS Rulemaking Requests. CMS has neither released agency records responsive to the request nor called or written Plaintiff about the requests since the October 27, 2005 telephone conversation.

34. On information and belief, CMS has no written published policy for first in first out processing of FOIA cases.

C. Plaintiff's Administrative Appeal, and CMS's Failure to Decide the Appeal.

35. After his conversation with Ms. Jones-Holman in late October 2005, Plaintiff prepared to appeal CMS's constructive denial of his August 2005 FOIA requests. However, he was unable to locate information regarding the identity or identities of the appeal officer(s) who hear FOIA appeals inside CMS. On information and belief, CMS has not provided to the public, whether in the form of regulations, guidance documents, or other written materials, the information needed to appeal a constructive denial of a FOIA request.

36. As of October 27, 2005, the CMS website indicated that Michael Marquis was the Director of the CMS FOIA Group. Plaintiff therefore prepared a letter, dated October 27, 2005, to Mr. Marquis, informing Mr. Marquis of Plaintiff's intention to appeal, and requesting information regarding where to send an administrative appeal. **Exhibit 3** to this Complaint is a true and correct copy of this letter. Plaintiff sent the letter via Federal Express on October 27, 2005. CMS received the letter on October 28, 2005. Plaintiff has not received a written response to his October 27 letter.

37. Following a voicemail left by plaintiff in the mailbox of Joseph Tripline of CMS on Nov. 4, 2005, Plaintiff received a return call from CMS's FOIA Group. The CMS message indicated that administrative FOIA appeals should be addressed to the Deputy Director of CMS.

38. Plaintiff prepared an administrative appeal and sent it to CMS's Deputy Director via Federal Express on November 5, 2005. Plaintiff sent the appeal in a Federal Express envelope clearly marked "FOIA Appeal." CMS received the appeal on November 7, 2005.

39. **Exhibit 4** to this Complaint is a true and correct copy of Plaintiff's administrative appeal to CMS, except that the protruding tabs for the four documents included with the original appeal have been replaced with un-tabbed pages indicating the numbering of the tabs.

40. As of the date of this Complaint, Plaintiff had not received an appeal decision or other communication from CMS regarding Plaintiff's administrative appeal. CMS has not decided Plaintiff's appeal.

41. HHS regulations applicable to CMS require that any decision on an administrative appeal be made after consultation with the General Counsel of HHS. 45 C.F.R. § 5.34(c). On information and belief, no such consultation has taken place with regard to Plaintiff's administrative appeal.

42. HHS regulations applicable to CMS require that any decision on an administrative appeal of a FOIA denial obtain the concurrence of the Assistant Secretary for Public Affairs. 45 C.F.R. § 5.34(c). On information and belief, the Assistant Secretary for Public Affairs has not been consulted regarding Plaintiff's administrative appeal.

D. CMS's Practice Of Not Deciding Most Administrative Appeals of FOIA Denials.

43. CMS's failure to decide Plaintiff's administrative appeal regarding his CMS Rulemaking FOIA Request is not surprising. As a general rule, CMS does not decide any given FOIA administrative appeal. CMS decisions on the merits of FOIA administrative appeals are rare. CMS's own annual reports demonstrate these facts.

44. Every year, CMS issues a "Freedom of Information Annual Report." These Annual Reports contains statistics about the agency's FOIA workload, backlog of

FOIA requests, number of person-equivalents devoted to responding to FOIA requests, and appeal data.

45. **Exhibits 5 and 6** to this Complaint are true and correct copies of the CMS FOIA Annual Reports (or at least the publicly-released portions) for Fiscal Years ("FYs") 2004 and 2003, respectively, as released by CMS through its website.

46. CMS's FOIA Annual Reports disclose, in their Sections VI ("Appeals of Initial Denials of FOIA/PA Requests") the following figures for administrative appeals "Received" and "Processed" for FYs 2004 and 2003:

Fiscal Year	Appeals Received	Appeals Processed
2004	31	4
2003	58	10

47. According to CMS's own data, for the recent period FY 2003 through FY 2004, CMS processed only 14 administrative appeals while receiving 89 appeals.

48. CMS's data regarding processing of appeals actually may overstate CMS's true efforts to decide appeals. CMS's annual reports do not provide backlog figures for appeals, i.e., data regarding appeals left over from previous years. Hence (and just for example) the four appeals CMS claims to have "processed" during FY 2004 well may have been appeals filed during previous years

49. Whether or not one gives full credence to CMS's figures for "processed" appeals, CMS's own data demonstrate that CMS generally does not decide FOIA appeals. Even if all the appeals "processed" during FY 2003 and FY 2004 actually were filed during those years, the result would be 14 decisions out of 89 appeals – or a decision rate of below 16 percent. For FY 2004 alone, 4 decisions out of 31 appeals would mean a

decision rate of just under 13 percent. Administrative appeals to CMS of FOIA denials, therefore, offer only the illusion and not the reality of a remedy for an initial denial of a FOIA request – as illustrated by Plaintiff's administrative appeal that has been ignored by CMS.

50. Administrative appeals to CMS of initial FOIA denials are futile.

V. Plaintiff's FOIA Requests to CMS-Chicago and to WPS.

51. Plaintiff has sought to obtain certain agency records from both CMS and from WPS, the private insurance carrier with which CMS contracts for administration of Medicare Plan B in the states of Illinois, Michigan, Wisconsin, and Minnesota.

52. In response to Plaintiff's FOIA requests, WPS has released to Plaintiff only limited and incomplete documentation, and in general has maintained that it lacks authority to release records. WPS generally has forwarded responsive records to one CMS office or another, where the records apparently remain to this day.

53. When Plaintiff has made requests made directly to CMS for information about WPS, CMS has passed the requests on to WPS.

54. The relationship between CMS and WPS with regard to FOIA operates in a way that essentially assures that none of the deadlines in the FOI Act or the HHS regulations ever will be met.

A. Background: Medicare Part B's Administration by Insurance Carriers, and the Carriers' Promulgation of LCDs.

55. When a Medicare Part B carrier receives a request for reimbursement from a provider, the carrier must decide whether to pay the claim. One question that arises with regard to a request for reimbursement is whether Medicare Part B covers the item or service for which the provider seeks reimbursement.

56. Section 1862(a)(1)(A) of the Medicare Act, as amended, 42 U.S.C. § 1395y(a)(1)(A), states, in part, that no payment may be made for any expenses and services that are not "reasonable and necessary" for the treatment or diagnosis of illness of injury or to improve the functioning of a malformed body member. When a carrier receives a request for reimbursement under Medicare Part B, therefore, the carrier must determine whether the expense or service for which reimbursement is sought is reasonable and necessary.

57. CMS addresses some coverage issues on a nationwide basis, by issuing what it calls (interchangeably) "National Coverage Determinations" or "National Coverage Decisions" (NCDs). When CMS issues an NCD, the various Medicare Part B carriers are required to follow the NCD, because the NCD defines what CMS considers reasonable and necessary.

58. When there is no NCD that addresses the service for which a provider seeks reimbursement, CMS leaves to the individual Medicare Part B carrier the decision whether the service is covered. As CMS has said expressly, "[i]n the absence of a specific national coverage decision, coverage decisions are made at the discretion of local contractors." 64 Fed. Reg. 22619, 22621, col. 1 (Apr. 27, 1999). Absent an NCD, therefore, Medicare Part B carriers determine what the statutory terms "reasonable" and "necessary" mean as applied to concrete circumstances within their jurisdictions.

59. CMS issues relatively few NCDs. Indeed, in a recent publication, CMS reported that "CMS only issues only about 18-24 NCDs each year," and that "about 90 percent of Medicare's coverage policies are made at the local level." (Fact Sheet: CMS

Responds to Stakeholder Feedback Regarding Coverage With Evidence Development, July 12, 2005, pp. 1-2).

60. In order to reduce ad hoc coverage decisions, CMS allows and indeed encourages Medicare Part B carriers to issue what are called "Local Coverage Determinations" (LCDs). LCDs are defined in 42 U.S.C. § 1395ff(f)(2)(B) to include, among other things, Medicare Part B carriers' decisions respecting whether a particular item or service is covered on a carrier-wide basis, in accordance with Medicare's "reasonable and necessary" requirement.

61. The LCDs issued by any given Medicare Part B carrier need not comport with the LCDs issued by other Medicare Part B carriers, and indeed may conflict with other carriers' LCDs.

62. In essence, LCDs represents determinations by Part B carriers regarding items or services that the carriers deem reasonable and necessary under the Medicare Act. LCDs reflect the carriers' decisions regarding how they will construe the statutory terms "reasonable" and "necessary" as applied to specified items and services, or classes of items or services.

B. WPS's Issuance of LCDs Regarding Flow Cytometry.

63. WPS issued LCDs regarding flow cytometry for four states in which it served as Medicare Part B carrier – Illinois, Wisconsin, Minnesota and Wisconsin. These LCDs bore "LCD ID Numbers" L16830, L16831, L16832, and L16833.

64. **Exhibits 7 through 10** to this Complaint are true and accurate copies of the WPS LCDs regarding flow cytometry, as set forth on the CMS website.

65. In promulgating its LCDs for the four states, WPS followed procedures required by CMS. WPS issued draft LCDs regarding flow cytometry and circulated the drafts for comment; held Advisory Committee meetings; received comments from interested members of the public; and ultimately issued final LCDs regarding flow cytometry. This process amounted to notice and comment rulemaking of a sort, conducted by an arm of CMS, with the result being LCDs applicable to four states, and reflecting WPS's construction of the statutory terms "reasonable" and "necessary" in the context of flow cytometry.

C. Plaintiff's FOIA Requests to CMS-Chicago Regarding WPS's LCDs.

66. Plaintiff submitted two FOIA requests, dated September 22, 2005, to CMS's Chicago office ("CMS-Chicago"). (The "CMS-Chicago Requests.") Both requests concerned Local Coverage Determinations made by WPS.

67. **Exhibits 11 and 12** to this Complaint are true and accurate copies of Plaintiff's FOIA requests to CMS-Chicago, save that these copies do not bear the Plaintiff's signature as it appears on the originals.

68. CMS-Chicago received Plaintiff's FOIA requests on September 30, 2005.

69. CMS-Chicago never sent correspondence of any kind to plaintiff. CMS-Chicago did not communicate with Plaintiff about the request until Plaintiff called CMS-Chicago to inquire about the status of the request.

70. On October 25, 2005, Plaintiff telephoned and spoke to Monica Perkins of CMS-Chicago. Ms. Perkins was listed on CMS's website as the Chicago FOIA contract, and was the addressee of Plaintiff's CMS-Chicago FOIA Requests.

71. On the October 25, 2005 telephone call from Plaintiff, Ms. Perkins indicated that CMS had "closed out" Plaintiff's CMS-Chicago FOIA Requests, and had sent them to the carrier on October 5. On that same call, Plaintiff requested a letter from CMS-Chicago regarding his FOIA requests. That request was to no avail, as CMS-Chicago never sent a letter to Plaintiff.

72. By letter dated November 17, 2005, WPS responded to one of Plaintiff's CMS-Chicago FOIA requests. **Exhibit 13** to this Complaint is a true and accurate copy of WPS's response, including attachments.

73. The WPS response included (besides a cover letter) only two documents, both of which refer to other records and sources of records. One of these documents appears to be an LCD, while the other appears to be a brief summary of comments received regarding a preliminary version of an LCD.

74. Both of the records released by WPS themselves demonstrate the existence, or likely existence, of additional records responsive to Plaintiff's FOIA requests. The LCD produced by WPS refers to "Advisory Committee Notes" regarding meetings that apparently took place on no fewer than six dates. One of Plaintiff's FOIA requests to CMS Chicago (**Exh. 11**) asked specifically – and only – for Advisory Committee Meeting Notes. The summary of comments document also makes clear that WPS received comments regarding the proposed LCD from a number of persons or entities. One of Plaintiff's FOIA requests to CMS-Chicago (**Exh.12**) requested, among other things, "all comments received by WPS regarding any interim or final LCD for flow cytometry that preceded L16830-33."

75. After receiving the Nov. 17 letter and documents from WPS, Plaintiff telephoned WPS to complain that the WPS response only partially fulfilled one of Plaintiff's two CMS-Chicago FOIA requests. Plaintiff enumerated the requested records that WPS's November 17, 2005 response did not include, such as WPS's draft LCD, the public comments on the draft, and notes regarding the LMRP.

76. As of December 1, 2005, Plaintiff had not heard back further from WPS regarding the CMS-Chicago FOIA requests. Plaintiff therefore followed up with FOIA requests sent directly to WPS.

D. Plaintiff's FOIA Requests Sent Directly to WPS.

77. On December 1, 2005, Plaintiff sent two FOIA request directly to WPS, via facsimile. **Exhibit 14** to this Complaint is a true and correct copy of Plaintiff's facsimile transmission to WPS (the "WPS Requests"). Plaintiff's WPS Requests contained virtually identical requests to those Plaintiff had set forth in his two September 22, 2005 CMS-Chicago Requests.

78. One of the FOIA requests contained in the fax transmission of Plaintiff's WPS Requests also asked WPS for information regarding FOIA appeal procedures. The letter included the following: "Finally, the last letter I received from WPS in response to a FOIA request did not contain information about whether and if so how I could take an administrative appeal of the response. If there are remedies you think I need to exhaust before seeking judicial review of your agency's response to this request, please let me know what they are in your response."

79. By letter dated January 3, 2006, WPS responded to Plaintiff's WPS FOIA Requests. **Exhibit 15** to this Complaint is a true and correct copy of the WPS response letter.

80. WPS's January 3, 2006 response letter asserted that records responsive to Plaintiff's request "are not within our authority to release." The letter added that WPS had forwarded responsive documents to CMS-Baltimore.

81. To date, CMS has neither released records responsive to Plaintiff's WPS FOIA Requests nor otherwise responded to those requests

E. Plaintiff's Request for FOIA Procedures Applicable to Medicare Part B Carriers, and the Delay That Has Followed.

82. By letter dated December 5, 2005, Plaintiff made a FOIA request to CMS. **Exhibit 23** to this Complaint is a true and correct copy of Plaintiff's December 5, 2005 FOIA request

83. Plaintiff's December 5, 2005 FOIA request asked for procedures, protocols, requirements, or guidelines that Medicare Part B Carriers such as WPS were required to follow in responding to FOIA requests, and procedures that members of the public must follow in order to take administrative appeals from denials of FOIA requests by Medicare Part B carriers.

84. CMS received Plaintiff's December 5, 2005 FOIA request on December 6, 2005.

85. CMS responded to Plaintiff's December 5, 2005 FOIA request by letter dated January 24, 2006. **Exhibit 24** to this Complaint is a true and correct copy of CMS's response letter. CMS's response to Plaintiff's December 5, 2005 FOIA request was CMS's standard form letter.

86. On information and belief, CMS forwarded Plaintiff's December 5, 2005 FOIA request to WPS, and WPS received the forwarded request on February 15, 2006.

87. WPS responded to Plaintiff's December 5, 2005 FOIA Request by a letter dated February 20, 2006. **Exhibit 17** to this Complaint is a true and correct copy of this letter.

88. WPS's February 20, 2006 letter referred to Plaintiff's "February 15, 2006, Freedom of Information Act (FOIA) request." On information and belief, the February 15, 2006 date was in fact the date on which WPS received Plaintiff's December 5, 2005 FOIA request, as forwarded by CMS.

89. In the February 20, 2006 letter, WPS again asserted that it did not have authority to release records requested by plaintiff, and again indicated that it had forwarded responsive records to CMS for review.

90. On April 19, 2006, Plaintiff telephoned Susan Hahn Reizner of CMS's Chicago office. Ms. Reizner was identified in the February 20, 2006 WPS letter as the one to whom WPS had forwarded responsive records. During the April 19 conversation, Ms. Reizner indicated that she had forwarded to CMS-Baltimore the records she had received from WPS, and that the new contact person in CMS for the FOIA request was Mr. Marquis at CMS-Baltimore.

91. Following his conversation with Ms. Reizner of CMS, Plaintiff left a voicemail message for Mr. Marquis of CMS, also on April 19, 2006. To date, Plaintiff has not received a response from Mr. Marquis or from anyone else in CMS, whether by telephone or in writing.

92. CMS-Chicago accomplished nothing with the records forwarded by WPS, other than to pass them along to Baltimore and further delay any response to Plaintiff's WPS FOIA request. CMS-Chicago's actions did not reflect due diligence in complying with FOIA, but instead merely wasted time.

93. To date, CMS has neither released records responsive to Plaintiff's December 5, 2005 FOIA Request, nor otherwise responded to that request, save for Ms. Reizner's indications, in the call initiated by Plaintiff on April 19, 2006, that she had forwarded to CMS-Baltimore the records she received from WPS.

94. The process utilized by CMS in response to Plaintiff's simple FOIA request about FOIA procedures has included pointless re-routings of paper, reflecting a system that effectively operates to ensure that the response deadlines contained in the FOIA (20 days) and HHS regulations (10 days) will not and cannot be met. There was no good reason to ship responsive documents from WPS to CMS-Chicago to CMS-Baltimore. Defendants have not shown due diligence in their responses to FOIA requests.

VI. Plaintiff's FOIA Requests to CMS Regarding CMS's FOIA Policies.

95. Plaintiff has sent CMS several FOIA requests seeking basic documentation of CMS's FOIA policies and procedures. Despite the apparent simplicity of fulfilling these requests – and the public's need to know basic agency procedures – CMS has yet to respond to these requests with anything but CMS's standard place-holding form letter.

A. Plaintiff's Requests for Documentation of CMS's Purported "First In First Out" Policy for Processing FOIA Requests.

96. By letter to CMS dated October 13, 2005, Plaintiff made a FOIA request to CMS. **Exhibit 18** to this Complaint is a true and correct copy of Plaintiff's October

13, 2005 Request, save that the copy does not bear the signature that Plaintiff affixed to the original.

97. Plaintiff's October 13, 2005 FOIA request asked CMS for records "that set forth CMS's policy of 'first in, first out' FOIA case processing." Plaintiff sent this request to CMS via USPS Priority Mail on October 14, 2005.

98. CMS received Plaintiff's October 13, 2005 Request on October 17, 2005. As of December 11, 2005, however, Plaintiff had received no response to his October 13, 2005 Request.

99. By letter dated December 11, 2005, Plaintiff repeated his FOIA request of October 13, and added a note to CMS that Plaintiff had made the same request two months earlier. **Exhibit 19** to this Complaint is a true and correct copy of Plaintiff's Dec. 11, 2005 FOIA request. Plaintiff sent this request to CMS by Federal Express on December 12, 2005, and CMS received it on December 13, 2005.

100. CMS responded to Plaintiff's October 13, 2005 FOIA request by letter dated January 25, 2006 – or more than three months after Plaintiff submitted the request. **Exhibit 20** to this Complaint is a true and accurate copy of CMS's response letter.

101. CMS's response to Plaintiff's October 13, 2005 FOIA request was CMS's standard form letter. To date, Plaintiff has received no further communication from CMS regarding this simple request.

102. So far as Plaintiff is aware, CMS never has responded to his December 11, 2005 FOIA request.

B. Plaintiff's Request to CMS for Records Showing Delegations of Authority to Decide FOIA Administrative Appeals.

103. By letter dated Nov. 3, 2005, Plaintiff made a FOIA request to CMS. **Exhibit 21** is a true and accurate copy of this request, save that Plaintiff's signature, while affixed to the original, does not appear on the copy.

104. Plaintiff's November 3, 2005 FOIA request asked for records showing delegations of authority to deny FOIA requests, and delegations of authority to decide appeals from CMS denials of FOIA requests.

105. By letter dated Nov. 22, 2005, CMS responded to Plaintiff's November 3, 2005 FOIA request. **Exhibit 22** is a true and correct copy of CMS's response letter.

106. The CMS response to Plaintiff's November 3, 2005 FOIA request was CMS's standard form letter. Since that letter, Plaintiffs has received no further communication from CMS regarding his request. CMS has neither released agency records responsive to Plaintiff's November 3, 2005 request, nor made a decision whether to release such records.

VII. Summary of Agency Responses To Plaintiff's FOIA Requests.

107. CMS itself has yet to release a single page of records to Plaintiff in response to any of the FOIA requests that are addressed in this Complaint. CMS's response to every FOIA request has been the same form letter that invokes an alleged "first in first out" policy.

108. The FOIA requests that Plaintiff has sent to CMS-Baltimore and as to as to which CMS has failed to release documents or to make a determination whether to comply are:

a. Plaintiff's two Aug. 29, 2005 requests regarding CMS's rulemaking (**Exh. 1**; CMS responses are **Exh. 2**);

b. Plaintiff's Oct. 13, 2005 request regarding CMS's purported "first in first out" policy for processing FOIA requests (**Exh. 18**; CMS response is **Exh. 20**);

c. Plaintiff's Dec. 11, 2005 request regarding CMS's purported "first in first out" policy for processing FOIA requests (**Exh. 19**; no CMS response);

d. Plaintiff's November 3, 2005 request regarding delegations of authority to CMS personnel to deny FOIA requests and to decide administrative appeals (**Exh. 21**; CMS response is **Exh. 22**); and

e. Plaintiff's December 5, 2005 FOIA request to CMS regarding FOIA procedures and FOIA administrative appeal procedures applicable to Medicare Part B carriers (**Exh. 23**; CMS response is **Exh. 24** and WPS response is **Exh. 17**).

109. The FOIA requests that Plaintiff submitted to CMS-Chicago and that garnered either no response or an incomplete response from WPS were Plaintiff's two requests dated Sept. 22, 2005 regarding a WPS rulemaking about reimbursement for flow cytometry procedures (**Exhs. 11 and 12**). CMS-Chicago did not supply any written response to these requests. A partial WPS response to one of the two requests is **Exh. 13**.

110. The FOIA requests submitted by plaintiff directly to WPS and as to which no records have been released are Plaintiff's requests dated December 1, 2005 regarding a WPS rulemaking related to Medicare Part B reimbursement for flow cytometry procedures (**Exh. 14**; WPS response is **Exh. 15**).

111. CMS has not released records even in response to simple requests regarding CMS's own FOIA practices and procedures – such as CMS's purported "first

in first out" policy or the delegation of authority to decide administrative appeals. CMS also has failed to decide Plaintiff's administrative appeal of a constructive FOIA denial, in keeping with CMS's pattern of essentially ignoring FOIA administrative appeals.

112. Plaintiff's FOIA requests to the Medicare Part B carrier WPS – or requests to CMS regarding the activities of WPS – have become mired in a bureaucratic bog. Of two requests regarding WPS that Plaintiff sent to CMS-Chicago, only one ultimately garnered any response, in the form of an incomplete release of records by WPS. When Plaintiff sent requests directly to WPS, WPS apparently found responsive records but then forwarded them to CMS; CMS has yet to release any of them. Finally, Plaintiff's request (sent to CMS-Baltimore) regarding FOIA procedures applicable to Part B carriers ended up, after considerably delay, at WPS. Again, WPS apparently found responsive records, but those records have passed from WPS to CMS-Chicago to CMS-Baltimore, and have yet to be released.

113. Defendants have not exercised, and are not exercising, due diligence to fulfill FOIA requests or to decrease CMS's backlog of FOIA requests.

VIII. CMS's Predictably-Increasing Backlog of FOIA Requests.

114. Over the past two fiscal years, CMS's backlog of initial FOIA requests has increased yearly. The following table sets forth correctly the year-end backlog figures reported by CMS, as reflected in the FY 2003 and FY 2004 FOIA Annual Reports for CMS (Exhs. 5 and 6), and the FY 2005 FOIA Annual Report for HHS. (**Exhibit 25** to this Complaint is a true and correct copy HHS's FY 2005 FOIA Annual Report.)

Fiscal Year	CMS Year-End Backlog
2005	4,935
2004	4,084
2003	3,073

115. The increase in CMS's backlog of outstanding FOIA requests was and is predictable. Among other things, CMS has reduced, year-by-year since FY 2003 both its full-time staff devoted to FOIA requests, and the work-years spent on FOIA requests by personnel working part-time on FOIA requests.

116. The following table sets forth the number of CMS personnel devoted full-time to FOIA requests, as well as number of personnel (or personnel-equivalents) with part-time or occasional FOIA duties, for the FYs 2003 through 2005, as set forth in the CMS and HHS annual FOIA reports:

Fiscal Year	Number of Full Time FOIA Personnel	No. of Personnel With Part Time Or Occasional FOIA Duties (work yrs)	Total No. of FOIA Personnel (in work yrs)
2005	70	11.8	81.8
2004	72	14.2	86.2
2003	74	15.2	89.2

117. For FY 2005, CMS's total number of personnel devoted to FOIA duties, as measured in work years, was more than eight percent lower than it was for FY 2003 (i.e., a reduction from 89.2 to 81.8). In this light, it is no surprise that CMS's backlog of FOIA requests has increased during the same period.

118. The number of FOIA initial requests submitted to CMS has increased over the period FY 2003 through 2005. However, this increase has in no way

been something in excess of what CMS and Congress could have anticipated: The volumes of requests CMS has received during the past three fiscal years have been well in line with the numbers for preceding fiscal years. The following table reflects the numbers of FOIA requests received by CMS, as reported in the official CMS and HHS Annual Reports regarding FOIA:

Fiscal Year	Number of Requests
2005	35,198
2004	32,725
2003	24,953
2002	29,341
2001	35,084
2000	32,403

119. As CMS's own Annual Reports on FOIA disclose, CMS received fewer FOIA requests during FY 2005 than it did during FY 2001. The number of FOIA requests received by CMS during FY 2005 fell well within the predictable agency workload of requests.

120. CMS is not making reasonable progress in reducing its backlog of outstanding FOIA requests. Indeed, CMS is not making any progress at all, as its backlog of pending FOIA requests continues to rise.

COUNT I

FREEDOM OF INFORMATION ACT

121. Plaintiff incorporates and re-alleges the allegations of all other paragraphs of this Complaint.

122. All records requested by Plaintiff in the FOIA requests that are the subjects of this action constitute "records" of an "agency" for purposes of the FOI Act and HHS regulations.

123. Plaintiff has exhausted or should be deemed to have exhausted his administrative remedies on a variety of independent grounds, including that:

a. For the August 2005 FOIA requests, Plaintiff filed an administrative appeal that CMS did not decide within the 20 days required by the FOIA, 5 U.S.C. § 552(a)(6)(A)(ii) and by the HHS regulations applicable to CMS and HHS, 45 C.F.R. § 5.35(b)(2).

b. For each of Plaintiff's FOIA requests, Defendants failed to respond with a "determin[ation] . . . whether to comply with such request . . . and the reasons therefore" within the 20 days required by FOIA. 5 U.S.C. § 552(a)(6)(A)(i). These failures constitute exhaustion pursuant to 5 U.S.C. § 552(a)(6)(C).

c. For all of Plaintiff's FOIA requests, Defendants failed to comply with the deadlines set by HHS regulations:

(1) HHS regulations require that HHS components such as CMS respond to FOIA requests within 10 days, 45 C.F.R. § 5.35(b)(1), and allow only one ten-day extension of this 10 day period, 45 C.F.R. § 5.35(c).

(2) The deadlines for response set forth in the HHS regulations are more stringent than those found in the FOIA, as amended. Because the amendments to the FOI Act that extended the FOIA response deadline from 10 to 20 days did not require HHS to change the deadlines in its regulations, the deadlines in the HHS regulations have not been changed by operation of law. HHS's FOIA regulations remain in force as they appear in the Code of Federal Regulations and in the Federal Register notice that set forth the current regulations. HHS issued an NPRM in 1999 that proposed changing the freedom of information deadlines for HHS components, but to date HHS has yet to issue a final rule changing the regulatory deadlines.

(3) HHS's own regulations further provide that if CMS or another HHS component agency fails to meet the regulations' deadlines, the requestor may proceed as if the agency had denied the requester's request or appeal. 45 C.F.R. § 5.35(a).

d. For all of Plaintiff's FOIA requests, Defendants failed to supply the necessary appeal information, including the identity and contact information for an appeal officer – even in response to FOIA requests seeking this very information.

e. There is no appeal process for a denial of, or an inadequate response to, a FOIA request made to WPS; and

f. Administrative appeals to CMS are futile, in that CMS routinely fails to decide the vast majority of the FOIA administrative appeals it receives.

124. Defendants' failure to timely decide Plaintiffs' FOIA requests violates the FOIA as well as applicable HHS regulations. Plaintiff has a statutory right to the record he seeks, and there is no legal justification for Defendants to withhold them.

COUNT II

ADMINISTRATIVE PROCEDURE ACT

125. Plaintiff incorporates and re-alleges the allegations of all other paragraphs of this Complaint.

126. Defendants' failures to respond timely to Plaintiff's FOIA requests, and the failure of CMS to decide Plaintiff's appeal in timely fashion (or at all), constitute agency actions unlawfully withheld and unreasonably delayed, in violation of the APA. Defendants' failures to respond timely and to decide plaintiff's appeal in timely fashion (or at all) also are arbitrary, capricious, an abuse of discretion, and without observance of procedure required by law, all in violation of the APA.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Order Defendants immediately to process the requested records in their entireties; to disclose the requested records in their entireties; and to make copies available to Plaintiff;

B. Award Plaintiff monetary relief such as his litigation costs and reasonable attorney fees; and

C. Grant such other relief as the Court may deem just and proper.

DATED: May 4, 2006

Respectfully submitted,

James T. O'Neill ARDC #6191496
325 West Huron Street, Suite 230
Chicago, Illinois 60610
Phone 312-602-3431
Fax 312-276-9183
jto@jto.com

Plaintiff

Table of Contents –

Exhibits to the Complaint

Exhibits to the Complaint (p.1 of 2)

Exh. No.	Description
1	Aug. 29, 2005 FOIA Requests (2) by Plaintiff to CMS
2	Sept. 9, 2005 CMS letters (2) to Plaintiff
3	Oct. 27, 2005 Plaintiff letter to Mr. Marquis, CMS
4	Nov. 5, 2005 Plaintiff FOIA appeal to CMS
5	CMS Annual FOIA Report, FY 2004
6	CMS Annual FOIA Report, FY 2003
7	LCD No. L16830, issued by WPS
8	LCD No. L16831, issued by WPS
9	LCD No. L16832, issued by WPS
10	LCD No. L16833, issued by WPS
11	Sept. 22 Plaintiff FOIA request to CMS-Chicago
12	Sept. 22 Plaintiff FOIA request to CMS-Chicago
13	Nov. 17, 2005 WPS letter to Plaintiff
14	Dec. 1, 2005 Plaintiff FOIA requests to WPS
15	Jan. 3, 2006 WPS letter to Plaintiff
16	Blank (no exhibit)
17	Feb. 20, 2006 WPS letter to Plaintiff
18	Oct. 13, 2005 Plaintiff FOIA request to CMS
19	Dec. 11, 2005 Plaintiff FOIA request to CMS
20	Jan. 25, 2006 CMS letter to Plaintiff
21	Nov. 3, 2005 Plaintiff FOIA request to CMS

Exhibits to the Complaint (p.2 of 2)

22	Nov. 22, 2005 CMS letter to Plaintiff
23	Dec. 5, 2005 Plaintiff FOIA request to CMS
24	Jan. 24, 2006 CMS letter to Plaintiff
25	HHS FOIA Annual Report for FY 2005

Exhibit 1

James T. O'Neill

411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Tel. (312)654-8685
Fax (312) 654-9893
JTO@jto.com

August 29, 2005

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Request Under Freedom of Information Act

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable agency regulations, I request the following agency records:

1. All records included in the "review of flow cytometry reports" referenced by CMS at page 49,048 (daily ed.) of the August 15, 2003 *Federal Register*. This *Federal Register* notice was entitled "Medicare Programs; Revisions to Payment Policies under the Physicians Fee Schedule for the Year 2004; Proposed Rule," and began at page 49,030 of the Aug, 15, 2003 daily edition.

2. All records other than rulemaking comments received from outside CMS considered by CMS in arriving at the position on flow cytometry set forth at page 63,216 (daily ed.) of the November 7, 2003 *Federal Register*. This *Federal Register* notice was entitled "Medicare Programs; Revisions to Payment Policies Under the Physicians Fee Schedule for the Year 2004; final rule With Comment Period," and began at page 63,196 (daily ed.) of the Nov. 7, 2003 *Federal Register*.

I agree in advance to pay charges of up to $300 for document search, review, and copying. If the charges are likely to exceed this amount, please let me know before exceeding $300 in charges.

Thank you in advance for you courtesy and cooperation.

Sincerely,

James T. O'Neill

Exhibit
1

James T. O'Neill

411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Tel. (312)654-8685
Fax (312) 654-9893
JTO@jto.com

August 29, 2005

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Request Under Freedom of Information Act

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Pursuant to the Freedom of Information Act and applicable agency regulations, I request the following agency records:

1. All records reflecting the indexing of the rulemaking docket for the rulemaking entitled "Medicare Programs; Revisions to Payment Policies under the Physicians Fee Schedule for the Year 2004."

The Proposed Rule for this docket appeared starting at page began at page 49,030 (daily ed.) of the Aug, 15, 2003 *Federal Register*, and the Final Rule appeared starting at page 63,216 (daily ed.) of the Nov. 7, 2003 *Federal Register*.

The "File Code" for this docket appears to have been CMS-1476-P.

My objective is to identify comments regarding flow cytometry issues, as discussed at page 63,216 of Nov. 7, 2003 *Federal Register*. If CMS has an index limited to those comments, I would be happy to receive a copy of it and forego anything else covered by this request.

I agree in advance to pay charges of up to $100 for document search, review, and copying. If the charges are likely to exceed this amount, please let me know before exceeding $100 in charges.

Thank you in advance for you courtesy and cooperation.

Sincerely,

James T. O'Neill

Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/ Freedom of Information Group

Refer to: C05FOI12250 (DJH)
SEP -9 2005

James T. O'Neill
411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request dated August 29, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

If you believe that your request should be expedited for any reason; i.e., such as a court date involving litigation, deadline for commenting on proposed regulations or other urgent matters, please notify us in writing and provide as much relevant information as possible. When submitting this additional information, please refer to the case number listed at the top left-hand corner of this letter, and send it to: Freedom of Information Group, N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

We are authorized by law to collect fees for responding to FOIA requests and assume that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250, we will send you an invoice for the full estimated costs and suspend further processing until payment of the invoiced amount is received. If estimated processing costs do not exceed $250, then we will send you an invoice for actual costs with our response.

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to:
Duncan Jones-Holman at (410) 786-9356

Exhibit
2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/ Freedom of Information Group

Refer to: C05FOI12251 (DJH)
SEP - 9 2005

James T. O'Neill
411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request dated August 29, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

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Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to:
Danean Jones-Holman at (410) 786-9356

Exhibit 3

James T. O'Neill
411 W Ontario Street
Suite 507
Chicago, Illinois 60610
(312) 654-8685

October 27, 2005

VIA FEDERAL EXPRESS

Mr. Michael Marquis
Director
Freedom of Information Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

RE: Intent to Appeal Constructive FOIA Denials, and Request for Information

Dear Mr. Marquis:

In late August, I submitted two FOIA requests to CMS. According to the USPS, CMS received these requests early in September. CMS assigned my requests the following reference numbers:

C05FOI12250 (DJH)
C05FOI12251 (DJH)

CMS's time to respond to my FOIA requests has come and gone, under both the FOI Act and the applicable HHS regulations. CMS's failure to provide a substantive response within the statutory deadlines constitutes constructive denial of my requests.

In order to exhaust my administrative remedies, I wish to take an administrative appeal of CMS's constructive denial of my requests. Unfortunately, I cannot find the name and address of the appropriate appeal body on the CMS website, in the HHS regulations, or anywhere else.

I request that CMS supply me with the necessary information to pursue an appeal. Specifically, I request the name and address of the agency official to whom I should address my appeals.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

cc: Hon. Barack Obama

Exhibit 3

Exhibit 4

James T. O'Neill
411 W Ontario Street
Suite 507
Chicago, Illinois 60610
(312) 654-8685

November 5, 2005

VIA FEDERAL EXPRESS

Deputy Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Mail Stop C5-16-03
Baltimore, Maryland 21244

RE: Freedom of Information Act Appeal

Dear Sir or Madam:

This is an appeal under the Freedom of Information Act.

On August 30, 2005, I submitted two requests (dated August 29) for agency records under the FOI Act and applicable agency regulations. (Copies of the requests are attached behind Tabs 1 and 2.).

In two letters dated September 9, 2005, CMS's FOIA Group assigned my requests the following reference numbers:

C05FOI12250 (DJH)
C05FOI12251 (DJH)

(Copies of the CMS response letters are attached behind Tabs 3 and 4.).[1]

The CMS letters were form letters, identical save for different reference numbers. The letters offered no substantive responses to my requests, but instead purported to invoke an alleged "policy" of "first in, first out" (hereinafter sometimes "FIFO"). The letters also gave no indication as to when I would receive records:

> "Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of 'first in, first out' case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible and you will be notified of our decision regarding release or non-release of those documents."

Exhibit 4

[1] Because CMS's responses were identical form letters, I do not know which of my two requests is the "12250" request and which one is designated "12251."

In the nearly two months that have elapsed since CMS's FOIA Group sent me those letters, I have received no further correspondence, and no indication as to when I will get my records.[2]

I now appeal CMS's constructive denial of my FOIA requests.

1. CMS Has Constructively Denied My FOIA Requests.

CMS received my FOIA requests two months ago. Every deadline contained in FOIA and the applicable regulations that conceivably could apply to my requests has passed.

CMS's failure to comply with the deadlines set by the FOI Act and HHS's regulations constitutes a constructive denial of my requests. For example, HHS's own regulations provide that "[i]f we fail to meet the deadlines, you may proceed as if we had denied your request." 45 C.F.R. § 5.35(a)(2004). See also 5 U.S.C. § 552(a)(6)(C)(i) (FOIA requestor "shall be deemed to have exhausted his administrative remedies . . . if the agency fails to comply with the applicable time limit provisions").

2. CMS's Failure to Reach Timely "Determinations" Regarding My Requests Violates the FOI Act and the Applicable HHS Regulations.

The FOI Act, as amended, requires that government agencies such as CMS must "determine within twenty [working] days . . . after receipt of any [FOIA] request whether to comply with such request and . . . immediately notify the person making such request of such determination and the reasons therefore . . .." 5 U.S.C. § 552(a)(6)(A)(i).

The HHS regulations regarding FOIA actually commit HHS components to the 10-day time limit contained in the FOI Act prior to the EFOIA Amendments of 1996. 45 C.F.R. § 5.35 (b)("We will decide whether to release records within 10 working days after your request reaches the appropriate FOIA office . . .."). While the 1996 Amendments gave HHS ample rationale for amending the regulations (using notice and comment rulemaking), to date HHS has retained the ten-day deadline.[3] CMS therefore is

[2] I attempted to obtain more information by telephoning Ms. Jones-Holman of CMS's FOIA Group, whose name and phone number appear in the footnote to the CMS form letter. While Ms. Jones-Holman was polite and professional, she declined to make any commitment regarding the timing of an agency response my requests. All I was able to ascertain was that my request had been forwarded to the "program office" on September 9, 2005, and that the Program Office also had a FIFO policy.

[3] During 1999, HHS published an NPRM that included a proposed 20-day deadline. HHS, Proposed Rule, Revision of the Department of Health and Human Services Freedom of Information Act Regulations and Implementation of the Electronic Freedom of Information Act Amendments of 1996, 64 Fed. Reg. 14668, 14673 (March 26, 1999)(proposing amended 5 C.F.R. § 5.35(b)(1)). To date, however, HHS has not issued a final rule.

bound by the 10-day deadline set forth in the regulations. Pearce v. Director, Office of Workers' Compensation Programs, 647 F. 2d 716, 726 (7th Cir. 1981)("[A]n agency is bound by its own regulations.").

Under limited circumstances, the FOI Act and the HHS regulations allow an extension of up to ten days in addition to the base of 20 days (FOIA) or 10 days (HHS regulations) for response to FOIA requests. 5 U.S.C. § 552 (a)(6)(B); 45 C.F.R. § 5.35(c). However, even if CMS conceivably could claim the benefit of the ten-day "unusual circumstances" extension here (despite not having mentioned the exception in its form letters), this extra ten day period would make no difference: CMS has had my requests for two months.

In short, CMS has failed to make timely "determinations" regarding my FOIA requests, in violation of the FOI Act and HHS regulations.

3. CMS's Alleged "First In-First Out" Policy Cannot Trump the FOIA Act or HHS's Regulations.

CMS's form letters assert that CMS has a "policy" of handling FOIA requests on a FIFO basis. CMS appears to contend that its choice of internal procedures -- FIFO versus some other scheme – somehow gives it a blanket license to ignore all FOIA deadlines. This is simply wrong.

So long as CMS complied with the law, its use of a FIFO method to process FOIA requests would be unobjectionable. To the extent that CMS paints its FIFO "policy" as some kind of shield against legal deadlines, however, CMS overreaches. If CMS truly has any kind of "policy" intended to overrule the deadlines set by the FOI Act and the HHS regulations,[4] this "policy" is a legal nullity.

First, CMS has no authority to second-guess or rewrite statutory law. CMS cannot ignore the deadlines established by Congress, any more than it can transmute the words "twenty days" (5 U.S.C. § 552(a)(6)(A)(i)) into the words "any time CMS gets around to it using a FIFO method." The FOIA is a mandate, not a suggestion.

Second, HHS's FOIA regulations contain time deadlines more stringent than those set by the FOI Act. CMS has no authority to rewrite portions of the Code of Federal Regulations by the expedient of a letter signed by a subordinate official. See, e.g., 5 C.F.R. § 5.3 ("Some units [of HHS] may establish additional [FOIA] rules . . . but such rules must be consistent with these rules and must have the concurrence of the Assistant Secretary for Public Affairs.").

[4] The CMS form letters do not cite to any publication in which CMS's supposed "policy" can be found, calling into doubt whether there really is such a "policy." See 45 C.F.R. § 5.3 (If additional [FOIA] rules are issued, they will be published in the FEDERAL REGISTER . . .."). If there were such a policy, CMS apparently created it without observance of Administrative Procedure Act requirements.

CMS's purported FIFO approach cannot conceivably trump the deadlines applicable to FOIA requests.

4. **CMS Should Release the Requested Records Forthwith.**

CMS has no legally cognizable defense for not complying with the deadlines set by the FOI Act and the corresponding HHS regulations.

In addition, CMS should have no need for more than a cursory review of the requested records before releasing them to me.

The records I have requested all relate to a (recent) public rulemaking. They should fall handily into the realm of what would have been considered the "administrative record" in a petition for judicial review of the regulations resulting from the rulemaking. As a result, it is difficult to conceive of any colorable basis for withholding them from release.

I respectfully request that CMS grant my appeal, and release to me the records I have requested.

Thank you for your consideration of this appeal.

Sincerely,

James T. O'Neill

Tab 1 to Nov. 5, 2005 FOIA Appeal

James T. O'Neill

411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Tel. (312)654-8685
Fax (312) 654-9893
JTO@jto.com

August 29, 2005

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Request Under Freedom of Information Act

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable agency regulations, I request the following agency records:

1. All records reflecting the indexing of the rulemaking docket for the rulemaking entitled "Medicare Programs; Revisions to Payment Policies under the Physicians Fee Schedule for the Year 2004."

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The "File Code" for this docket appears to have been CMS-1476-P.

My objective is to identify comments regarding flow cytometry issues, as discussed at page 63,216 of Nov. 7, 2003 *Federal Register*. If CMS has an index limited to those comments, I would be happy to receive a copy of it and forego anything else covered by this request.

I agree in advance to pay charges of up to $100 for document search, review, and copying. If the charges are likely to exceed this amount, please let me know before exceeding $100 in charges.

Thank you in advance for you courtesy and cooperation.

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James T. O'Neill

Tab 2 to Nov. 5, 2005 FOIA Appeal

James T. O'Neill

411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Tel. (312)654-8685
Fax (312) 654-9893
JTO@jto.com

August 29, 2005

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
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Sincerely,

James T. O'Neill

Tab 3 to Nov. 5, 2005 FOIA Appeal

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/ Freedom of Information Group

Refer to: C05FO112250 (DJH)
SEP -9 2005

James T. O'Neill
411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request dated August 29, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

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Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to:
Danean Jones-Holman at (410) 786-9356

Tab 4 to Nov. 5, 2005 FOIA Appeal

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/ Freedom of Information Group

Refer to: C05FOI12251 (DJH)
SEP - 9 2005

James T. O'Neill
411 West Ontario Street
Suite 507
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request dated August 29, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

If you believe that your request should be expedited for any reason; i.e., such as a court date involving litigation, deadline for commenting on proposed regulations or other urgent matters, please notify us in writing and provide as much relevant information as possible. When submitting this additional information, please refer to the case number listed at the top left-hand corner of this letter, and send it to: Freedom of Information Group, N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

We are authorized by law to collect fees for responding to FOIA requests and assume that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250, we will send you an invoice for the full estimated costs and suspend further processing until payment of the invoiced amount is received. If estimated processing costs do not exceed $250, then we will send you an invoice for actual costs with our response.

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to:
Danean Jones-Holman at (410) 786-9356

Exhibit 5

FREEDOM OF INFORMATION ANNUAL REPORT – FISCAL YEAR 2004

I. AGENCY **Centers for Medicare & Medicaid Services**

REPORT PREPARED BY **MICHAEL S. MARQUIS**

TITLE **Freedom of Information Group**

ADDRESS **7500 Security Boulevard, North Building, N2-20-16, Baltimore, Maryland 21244**

PHONE NUMBER **(410) 786-5352**

ELECTRONIC ADDRESS FOR REPORT ON THE WORLD WIDE WEB:

http://www.cms.hhs.gov/foia/annrpts.asp

ADDRESS FOR PAPER COPIES OF REPORT:

(SAME AS ABOVE)

II. HOW TO MAKE A FOIA REQUEST:
http://www.cms.hhs.gov/foia/making.asp
(Describe or provide electronic address for instructions in FOIA reference guide)

A. Names, addresses, and telephone numbers of all individual agency components and offices that process FOIA requests (do not include coordinating offices; do not use persons' names – only titles):

http://www.cms.hhs.gov/foia/contacts.asp

B. Brief description of agency's response time range(s):

The agency's response time ranges from as little as **5** days for simple FOIA requests that seek documents that may be directly released to requesters by CMS program offices, to upwards of **38** months for complex FOIA requests that seek records that must be reviewed against the FOIA exemptions and processed in accordance with the agency's first-in, first-out practice.

Exhibit 5

C. Brief description of why some requests are not granted:

Requests are not granted in order to preserve the confidentiality of sensitive personal, commercial and government information within CMS's possession and control, and to protect the effective and efficient operations of the agency. To this end, the exemptions most often applicable to CMS records are Exemptions 2, 4, 5, 6, and 7. This agency's decision to deny access to a record (or portion thereof) is made only after application of the Attorney General's "foreseeable harm" standard.

III. DEFINITIONS OF TERMS AND ACRONYMS USED IN REPORT:

A. Agency-specific acronyms or other terms:
None

B. Basic terms (from FOIA UPDATE , Summer 1997):
CMS uses all terms from FOIA Update, Summer 1997.

IV. EXEMPTION 3 STATUTES:

A. List of Exemption 3 statutes relied on by the agency during report year:
41 U.S.C. 253b(m)

1. Brief description of type(s) of information withheld under each statute:

Statute/Rule	Type of Information Withheld	Case Citation
41 U.S.C. 253b(m)	Any proposal submitted by a contractor in response to the requirements of a solicitation of a competitive proposal, if such proposal is not set forth or incorporated by reference in the ensuing contract.	None

2. Has a court upheld the use of each statute? If so, cite example: **No**.

V. INITIAL FOIA/PA ACCESS REQUESTS (Include all requests, 3rd or 1st party):

A. Numbers of initial requests (line 1 + line 2 - line 3 = line 4):

1. Number of requests pending at close of preceding fiscal year: **3,073**

2. Number of requests received during reporting fiscal year **32,725**

3. Number of requests processed during reporting fiscal year: **31,714**

4. Number of requests pending at close of reporting fiscal year: **4,084**
(Enter this number also as Line VII.B.1.)

B. Disposition of Initial Requests:

1. Number granted in full: **24,572**

2. Number granted in part: **65**

3. Number of full denials: **1,956**

a. Number of times each FOIA exemption was used:

Exemption 1	**0**
Exemption 2	**3**
Exemption 3	**2**
Exemption 4	**7**
Exemption 5	**29**
Exemption 6	**1,996**
Exemption 7	**8 = 7a=3, 7c=5,**
Exemption 8	**0**
Exemption 9	**0**

4. Other reasons for non-disclosure (total) **5,121**

a. no records **2,269**
b. referrals **21**
c. request withdrawn **429**
d. fee-related reason **450**
e. records not reasonably described **1,119**
f. not a proper FOIA request for some other reason **756**
g. not an agency record **0**
h. duplicate request **3**
i. other (specify) **74 (cancellations, admin closures)**

VI. APPEALS OF INITIAL DENIALS OF FOIA/PA REQUESTS (include all access requests whether first or third party):

A. Numbers of Appeals:

1. Number of appeals received during the fiscal year **31**

2. Number of appeals processed during the fiscal year **4**

B. Disposition of Appeals:

1. Number completely upheld **0**

2. Number partially reversed **2**

3. Number completely reversed **0**

a. Number of times each FOIA exemption used (counting each exemption used once per appeal)

Exemption 1 **0**
Exemption 2 **0**
Exemption 3 **0**
Exemption 4 **0**
Exemption 5 **0**
Exemption 6 **0**
Exemption 7 **0**
Exemption 7(A) **0**
Exemption 7(B) **0**
Exemption 7 (C) **0**
Exemption 7(D) **0**
Exemption 7(E) **0**
Exemption 7(F) **0**
Exemption 8 **0**
Exemption 9 **0**

4. Other reasons for non-disclosure (total) **2**

a. no records **0**
b. referrals **0**
c. request withdrawn **0**
d. fee-related reason **0**
e. records not reasonably described **0**
f. not a proper FOIA request for some other reason **0**
g. not an agency record **0**
h. duplicate request **0**
i. other (specify) **2** (cancellations, admin closures)

VII. COMPLIANCE WITH TIME LIMITS/STATUS OF PENDING REQUESTS:

A. Median Processing Time for Requests Processed During the Year.

1. Simple Requests (if multiple tracks used):
   a. number of requests processed **31,051**
   b. median number of days to process **9**
2. Complex Requests (specify for any and all tracks used):
   a. number of requests processed **652**
   b. median number of days to process **77**

3. Requests Accorded Expedited Processing:
   a. number of requests processed **11**
   b. median number of days to process **66**

B. Status of Pending Requests (if multiple tracks are being used, report for each track as well as totals).

1. Number of requests pending as of the end of the fiscal year covered in this report (from Line V.A.4): **4,084**
   a. Simple Requests **2,272**
   b. Complex Requests **1,812**

2. Median number of days that such requests were pending as of that date
   a. Simple Requests **10.5**
   b. Complex Requests Unknown

VIII. COMPARISONS WITH PREVIOUS YEARS(S) (Optional):

IX. COSTS/FOIA STAFFING:

A. Staffing levels:

1. Number of full-time FOIA personnel **72**

2. Number of personnel with part-time or occasional FOIA duties (in total work-years **14.2**

3. Total number of personnel (in work years) **86.2**

B. Total costs (including staff and all resources):

1. FOIA processing (including appeals) **$ 2,179,180**

2. Litigation-related activities (estimated) **$ 105,000**

3. Total costs **$ 2,284,180**

4. Comparison with previous year(s) (including percentage of change) (optional)

X. FEES:

A. Total fees collected by agency for processing requests: **$240,279**

B. Percentage of total costs: **10.5**

XI. FOIA REGULATIONS (including fee schedule):

Exhibit 6

FREEDOM OF INFORMATION ANNUAL REPORT – FISCAL YEAR 2003

I.AGENCY **Centers for Medicare & Medicaid Services**

REPORT PREPARED BY **LEE J. JACKSON**

TITLE **Freedom of Information Group**

ADDRESS **7500 Security Boulevard, North Building, N2-20-16, Baltimore, Maryland 21244**

PHONE NUMBER **(410) 786-5352**

ELECTRONIC ADDRESS FOR REPORT ON THE WORLD WIDE WEB:

http://www.cms.hhs.gov/foia/annrpts.asp

ADDRESS FOR PAPER COPIES OF REPORT:

(SAME AS ABOVE)

II. HOW TO MAKE A FOIA REQUEST:
http://www.cms.hhs.gov/foia/making.asp
(Describe or provide electronic address for instructions in FOIA reference guide)

A. Names, addresses, and telephone numbers of all individual agency components and offices that process FOIA requests (do not include coordinating offices; do not use persons' names – only titles):

http://www.cms.hhs.gov/foia/contacts.asp

B. Brief description of agency's response time range(s):

The agency's response time ranges from as little as 7 days for simple FOIA requests that seek documents that may be directly released to requesters by CMS program offices, to upwards of 3 months for complex FOIA requests that seek records that must be reviewed against the FOIA exemptions and processed in accordance with the agency's first-in, first-out practice.

Exhibit 6

C. Brief description of why some requests are not granted:

Requests are not granted in order to preserve the confidentiality of sensitive personal, commercial and government information within CMS's possession and control, and to protect the effective and efficient operations of the agency. To this end, the exemptions most often applicable to CMS records are Exemptions 2, 4, 5, 6, and 7. This agency's decision to deny access to a record (or portion thereof) is made only after application of the Attorney General's "foreseeable harm" standard.

III DEFINITIONS OF TERMS AND ACRONYMS USED IN REPORT:

A. Agency-specific acronyms or other terms:
None

B. Basic terms (from FOIA UPDATE , Summer 1997):
CMS uses all terms from FOIA Update, Summer 1997.

IV EXEMPTION 3 STATUTES:

A. List of Exemption 3 statutes relied on by the agency during report year:
1. **41 U.S.C. 253b(m)**
2. **42 U.S.C. 1320 (c)(9)**

1. Brief description of type(s) of information withheld under each statute:

Statute/Rule	Type of Information Withheld	Case Citation
41 U.S.C. 253b(m)	Any proposal submitted by a contractor in response to the requirements of a solicitation of a competitive proposal, if such proposal is not set forth or incorporated by reference in the ensuing contract.	None
42 U.S.C. 1320 (c) (9)	Information created or acquired by a Peer Review organization in the exercise of its duties and functions.	

2. Has a court upheld the use of each statute? If so, cite example: **No**.

V. INITIAL FOIA/PA ACCESS REQUESTS (Include all requests, 3rd or 1st party):

A. Numbers of initial requests (line 1 + line 2 - line 3 = line 4):

1. Number of requests pending at close of preceding fiscal year: **3,812**

2. Number of requests received during reporting fiscal year **24,953**

3. Number of requests processed during reporting fiscal year: **25,692**

4. Number of requests pending at close of reporting fiscal year: **3,073**
(Enter this number also as Line VII.B.1.)

B. Disposition of Initial Requests:

1. Number granted in full: **21,164**

2. Number granted in part: **60**

3. Number of full denials: **1,327**

a. Number of times each FOIA exemption was used:

Exemption 1 **0**
Exemption 2 **12**
Exemption 3 **19**
Exemption 4 **21**
Exemption 5 **58**
Exemption 6 **1,385**
Exemption 7 **10 = 7a=2, 7c=5, 7d=1, 7e=2**
Exemption 8 **0**
Exemption 9 **0**

4. Other reasons for non-disclosure (total) **3,141**

a. no records **1,003**
b. referrals **32**
c. request withdrawn **380**
d. fee-related reason **652**
e. records not reasonably described **46**
f. not a proper FOIA request for some other reason **808**
g. not an agency record **2**
h. duplicate request **2**
i. other (specify) **216** (cancellations, admin closures)

VI. APPEALS OF INITIAL DENIALS OF FOIA/PA REQUESTS (include all access requests whether first or third party):

A. Numbers of Appeals:

1. Number of appeals received during the fiscal year **58**

2. Number of appeals processed during the fiscal year **10**

B. Disposition of Appeals:

1. Number completely upheld **0**

2. Number partially reversed **2**

3. Number completely reversed **0**

   a. Number of times each FOIA exemption used (counting each exemption used once per appeal)

      Exemption 1 **0**
      Exemption 2 **0**
      Exemption 3 **0**
      Exemption 4 **1**
      Exemption 5 **1**
      Exemption 6 **0**
      Exemption 7 **0**
      Exemption 7(A) **0**
      Exemption 7(B) **0**
      Exemption 7 (C) **0**
      Exemption 7(D) **0**
      Exemption 7(E) **0**
      Exemption 7(F) **0**
      Exemption 8 **0**
      Exemption 9 **0**

4. Other reasons for non-disclosure (total) **8**
   a. no records _____
   b. referrals **0**
   c. request withdrawn **8**
   d. fee-related reason **0**
   e. records not reasonably described **0**
   f. not a proper FOIA request for some other reason **0**
   g. not an agency record **0**
   h. duplicate request _____
   i. other (specify) _____(cancellations, admin closures)

VII. COMPLIANCE WITH TIME LIMITS/STATUS OF PENDING REQUESTS:

A. Median Processing Time for Requests Processed During the Year.

1. Simple Requests (if multiple tracks used):
   a. number of requests processed **24,530**
   b. median number of days to process **9**
2. Complex Requests (specify for any and all tracks used):
   a. number of requests processed **1,148**
   b. median number of days to process **84**

3. Requests Accorded Expedited Processing:
   a. number of requests processed **14**
   b. median number of days to process **76**

B. Status of Pending Requests (if multiple tracks are being used, report for each track as well as totals).

1.Number of requests pending as of the end of the fiscal year covered in this report (from Line V.A.4): **3,073**
   a. Simple Requests **2,168**
   b. Complex Requests **905**

2. Median number of days that such requests were pending as of that date
   a. Simple Requests **7**
   b. Complex Requests Unknown

VIII. COMPARISONS WITH PREVIOUS YEARS(S) (Optional):

IX. COSTS/FOIA STAFFING:

A. Staffing levels:

1. Number of full-time FOIA personnel **74**

2. Number of personnel with part-time or occasional FOIA duties (in total work-years **15.2**

3. Total number of personnel (in work years) **89.2**

B. Total costs (including staff and all resources):

1. FOIA processing (including appeals) **$ 2,185,341**

2. Litigation-related activities (estimated) **$ 51,508**

3. Total costs **$ 2,236,849**

4. Comparison with previous year(s) (including percentage of change) (optional)

X. FEES:

A. Total fees collected by agency for processing requests: **$215,104**

B. Percentage of total costs: **9.6%**

XI. FOIA REGULATIONS (including fee schedule):

Exhibit 7

Medicare Coverage Database

LCD for FLOW CYTOMETRY (L16830)

Jump to Section...

Please note: If you are printing this document and it is truncated on the right margin, please try printing landscape.

Contractor Information

Contractor Name back to top

Wisconsin Physicians Service Insurance Corporation

Contractor Number back to top

00951

Contractor Type back to top

Carrier

LCD Information

LCD ID Number back to top

L16830

LCD Title back to top

FLOW CYTOMETRY

Contractor's Determination Number back to top

PATH-016

Exhibit 7

AMA CPT / ADA CDT Copyright Statement back to top

CMS National Coverage Policy back to top

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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Wisconsin

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Region V

Original Determination Effective Date back to top

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Revision Ending Date back to top

Indications and Limitations of Coverage and/or Medical Necessity back to top

Description

Flow Cytometry is a cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. Data is generated and organized by the instrument. Clinical analysis and interpretations are performed by an experienced physician, usually a hemopathologist.

- Immunophenotyping (88180) Flow cytometry; each cell surface marker

  Immunophenotyping is indicated for the following conditions:

  - **HIV infection**

    The status of an HIV-infected patient can be monitored by the analysis of the surface antigen CD4 and CD8. This information can contribute to a prognosis as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem or therapy change, it may be necessary to perform the test at an increased frequency.

    Note: In addition to flow cytometry other tests are used to evaluate and follow this disease such as: T-cell; total count (86359) and or T cell absolute CD4 and CD8 count including ration (86360). On initial evaluation, additional T cell markers may be indicated.

  - **Drug monitoring**

    Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. (Examples of 2 drugs that would fit into this category are Alefacept and Alemtuzamab)

  - **Leukemia or Lymphoma**

    Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Sometimes, flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an antibody panel for appropriate differential diagnosis and classification. This process is sometimes necessary at the initial diagnostic phase, for separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either denovo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen can usually distinguish between potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has already established a diagnosis, and where the neoplastic cells have a characteristic phenotype, may be unnecessary to extensively re-phenotype the lesion; instead, using a limited analysis that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach is probably not appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse are not uncommon.

Leukemia:

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal B lymphocytosis. It can also define certain atypical gains and losses of T cell related antigens that are associated with clonal T cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple "pan" cell and T cell differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T or B cell leukemias.

In the situation of plasma cell dyscrasias (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T or B lineage. For the B cell lineage certain differentiation antigens are prognostically useful.

The acute leukemic panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

Lymphoma

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test and is not always necessary in the diagnosis and staging of every lymphoma. However some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy

(FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panel of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complimentary approaches. The first and newest is to use well-defined panels of 10-12 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical co-expression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell dyscrasia (e.g. plasma cytoma) a smaller panel directed at both cell surface, immunoglobulin light chains and cytoplasmic immunoglobulin light chains, would be appropriate.

Flow cytometry can help define NK cell lineage is rare neoplastic NK proliferations. However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist.

The panel would be performed in stages and may include up to 18 antibodies for lymphomas.

- **Transplants:**

Organ Transplants:

Postoperative monitoring of organ transplants may be necessary to determine early

rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection. The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Stem cell transplants:

To measure CD34 stem cell counts (e.g., CD34, CD45) in patients undergoing autologous transplantation.

- **Primary Immunodeficiencies**

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation.

- **Paroxysmal nocturnal hemoglobinuria**

Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing the red and white blood cells by flow cytometry for the absence of these antigens. In general staining the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and with antibodies to some of the missing antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

- **Hereditary persistence of fetal hemoglobin (HPFH)**

Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modify the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

- **Hereditary Spherocytosis**

  A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

- **HLA B27**

  An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay (86812) that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure.

- DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase) (88182) Flow cytometry; cell cycle or DNA analysis.

- **Carcinomas**

  DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are:

  Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

  Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize.

It has not been proven that this testing provides useful information in colorectal or breast cancers.

This is usually performed only one time after a diagnosis has been made and before treatment is initiated.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:

- Prostatic adenocarcinoma
- Urinary Bladder Carcinoma
- Ovarian Carcinoma
- Endometrial adenocarcinoma
- Renal cell adenocarcinoma
- Mediastinal neuroblastoma
- Medulloblastoma

- **Molar Pregnancies**
  Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles which are triploid can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

Coverage Topic back to top

Category Undefined

Coding Information

Bill Type Codes: back to top

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x	Not Applicable

Revenue Codes: back to top

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally

to all Revenue Codes.

99999	Not Applicable

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88180	FLOW CYTOMETRY; EACH CELL SURFACE, CYTOPLASMIC OR NUCLEAR MARKER
88182	FLOW CYTOMETRY; CELL CYCLE OR DNA ANALYSIS
88184	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; FIRST MARKER
88185	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; EACH ADDITIONAL MARKER (LIST SEPARATELY IN ADDITION TO CODE FOR FIRST MARKER)
88187	FLOW CYTOMETRY, INTERPRETATION; 2 TO 8 MARKERS
88188	FLOW CYTOMETRY, INTERPRETATION; 9 TO 15 MARKERS
88189	FLOW CYTOMETRY, INTERPRETATION; 16 OR MORE MARKERS

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CPT codes 88184-88189 are indicated for the following conditions:
(88180-Flow cytometry; each cell surface marker was deleted effective 12/31/2004)

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
079.51	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE I [HTLV-I]
079.52	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE II [HTLV-II]
079.53	HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 [HIV-2]
099.3	REITER'S DISEASE
200.00 - 203.81	RETICULOSARCOMA UNSPECIFIED SITE - OTHER IMMUNOPROLIFERATIVE NEOPLASMS IN REMISSION
204.00 - 208.91	LYMPHOID LEUKEMIA ACUTE WITHOUT REMISSION - UNSPECIFIED LEUKEMIA IN REMISSION
238.6	NEOPLASM OF UNCERTAIN BEHAVIOR OF PLASMA CELLS
238.7	NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
273.1	MONOCLONAL PARAPROTEINEMIA
273.3	MACROGLOBULINEMIA
279.10 - 279.9	IMMUNODEFICIENCY WITH PREDOMINANT T-CELL DEFECT UNSPECIFIED - UNSPECIFIED DISORDER OF IMMUNE MECHANISM
282.0	HEREDITARY SPHEROCYTOSIS

282.5	SICKLE-CELL TRAIT
282.60 - 282.69	SICKLE-CELL DISEASE UNSPECIFIED - OTHER SICKLE-CELL DISEASE WITH CRISIS
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720.0 - 720.9	ANKYLOSING SPONDYLITIS - UNSPECIFIED INFLAMMATORY SPONDYLOPATHY
795.4	OTHER NONSPECIFIC ABNORMAL HISTOLOGICAL FINDINGS
996.80 - 996.89	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN
V42.0 - V42.89	KIDNEY REPLACED BY TRANSPLANT - OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS

CPT code 88182 (Flow cytometry; cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:

164.2	MALIGNANT NEOPLASM OF ANTERIOR MEDIASTINUM
164.3	MALIGNANT NEOPLASM OF POSTERIOR MEDIASTINUM
182.0	MALIGNANT NEOPLASM OF CORPUS UTERI EXCEPT ISTHMUS
183.0	MALIGNANT NEOPLASM OF OVARY
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA
185	MALIGNANT NEOPLASM OF PROSTATE
188.0 - 188.9	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
189.0	MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS
189.1	MALIGNANT NEOPLASM OF RENAL PELVIS
191.0 - 191.8	MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES - MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN
630	HYDATIDIFORM MOLE

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N/A

ICD-9 Codes that DO NOT Support Medical Necessity back to top

N/A

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N/A

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Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

Documentation in the progress notes and/or in the pathology report(s) must reflect medical necessity, and be available on request.

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Routine use of flow cytometry in situations where the test is performed on tissue or tumor tissue, is not covered. Documentation in the patient's record must demonstrate how the results would impact the treatment plan.

Acute leukemia: Up to 20 antibodies may be required to adequately characterize acute leukemia.

Chronic lymphoproliferative disorder (CLD): Up to 18 antibodies may be required to adequately characterize CLD.

Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.

Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame does not provide any additional information and therefore would be considered not medically necessary.

Flow cytometry used as part of experimental protocols is not a covered service.

This is a revision of policies PATH 96-04 in Minnesota and PATH 016 in Wisconsin. It is a new policy for Illinois and Michigan.

Comments

- Terms:

  ploidy: The number of single sets of chromosomes in a cell or organism.
  diploid: Having two sets or a pair of chromosomes as normally found in the somatic cell of higher organisms. A diploid cell has one chromosome from each parent.
  triploid: Having three times the haploid number of chromosomes in the cell nucleus and would be abnormal in humans.

  aneuploid: Having a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploid cell would be considered abnormal. A triploid cell would be an example of aneuploidy in humans.

- Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.

Sources of Information and Basis for Decision back to top

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Updated on 05/04/2004 with effective dates 11/15/2003 - 12/31/2004

Read the LCD Disclaimer

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Exhibit 8

Medicare Coverage Database

LCD for FLOW CYTOMETRY (L16831)

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00952

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Carrier

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L16831

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FLOW CYTOMETRY

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PATH-016

Exhibit 8

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CMS National Coverage Policy back to top

Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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Description

Flow Cytometry is a cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. Data is generated and organized by the instrument. Clinical analysis and interpretations are performed by an experienced physician, usually a hemopathologist.

- Immunophenotyping (88180) Flow cytometry; each cell surface marker

  Immunophenotyping is indicated for the following conditions:

  - **HIV infection**

    The status of an HIV-infected patient can be monitored by the analysis of the surface antigen CD4 and CD8. This information can contribute to a prognosis as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem or therapy change, it may be necessary to perform the test at an increased frequency.

    Note: In addition to flow cytometry other tests are used to evaluate and follow this disease such as: T-cell; total count (86359) and or T cell absolute CD4 and CD8 count including ration (86360). On initial evaluation, additional T cell markers may be indicated.

  - **Drug monitoring**

    Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. (Examples of 2 drugs that would fit into this category are Alefacept and Alemtuzamab)

  - **Leukemia or Lymphoma**

    Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Sometimes, flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an antibody panel for appropriate differential diagnosis and classification. This process is sometimes necessary at the initial diagnostic phase, for separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either denovo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen can usually distinguish between potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has already established a diagnosis, and where the neoplastic cells have a characteristic phenotype, may be unnecessary to extensively re-phenotype the lesion; instead, using a limited analysis that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach is probably not appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse are not uncommon.

Leukemia:

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal B lymphocytosis. It can also define certain atypical gains and losses of T cell related antigens that are associated with clonal T cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple "pan" cell and T cell differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T or B cell leukemias.

In the situation of plasma cell dyscrasias (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T or B lineage. For the B cell lineage certain differentiation antigens are prognostically useful.

The acute leukemic panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

Lymphoma

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test and is not always necessary in the diagnosis and staging of every lymphoma. However some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy

(FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panel of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complimentary approaches. The first and newest is to use well-defined panels of 10-12 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical co-expression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell dyscrasia (e.g. plasma cytoma) a smaller panel directed at both cell surface, immunoglobulin light chains and cytoplasmic immunoglobulin light chains, would be appropriate.

Flow cytometry can help define NK cell lineage is rare neoplastic NK proliferations. However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist.

The panel would be performed in stages and may include up to 18 antibodies for lymphomas.

- **Transplants:**

Organ Transplants:

Postoperative monitoring of organ transplants may be necessary to determine early

rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection. The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Stem cell transplants:

To measure CD34 stem cell counts (e.g., CD34, CD45) in patients undergoing autologous transplantation.

- **Primary Immunodeficiencies**

  Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation.

- **Paroxysmal nocturnal hemoglobinuria**
  Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing the red and white blood cells by flow cytometry for the absence of these antigens. In general staining the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and with antibodies to some of the missing antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

- **Hereditary persistence of fetal hemoglobin (HPFH)**
  Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modify the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

- **Hereditary Spherocytosis**

  A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

- **HLA B27**

  An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay (86812) that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure.

- DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase) (88182) Flow cytometry; cell cycle or DNA analysis.

- **Carcinomas**

  DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are:

  Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

  Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize.

It has not been proven that this testing provides useful information in colorectal or breast cancers.

This is usually performed only one time after a diagnosis has been made and before treatment is initiated.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:

- Prostatic adenocarcinoma
- Urinary Bladder Carcinoma
- Ovarian Carcinoma
- Endometrial adenocarcinoma
- Renal cell adenocarcinoma
- Mediastinal neuroblastoma
- Medulloblastoma

- **Molar Pregnancies**
  Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles which are triploid can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

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Lab Services

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795.4	OTHER NONSPECIFIC ABNORMAL HISTOLOGICAL FINDINGS
996.80 - 996.89	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN
V42.0 - V42.89	KIDNEY REPLACED BY TRANSPLANT - OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS

CPT code 88182 (Flow cytometry; cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:

164.2	MALIGNANT NEOPLASM OF ANTERIOR MEDIASTINUM
164.3	MALIGNANT NEOPLASM OF POSTERIOR MEDIASTINUM
182.0	MALIGNANT NEOPLASM OF CORPUS UTERI EXCEPT ISTHMUS
183.0	MALIGNANT NEOPLASM OF OVARY
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA
185	MALIGNANT NEOPLASM OF PROSTATE
188.0 - 188.9	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
189.0	MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS
189.1	MALIGNANT NEOPLASM OF RENAL PELVIS
191.0 - 191.8	MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES - MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN
630	HYDATIDIFORM MOLE

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N/A

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N/A

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N/A

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Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

Documentation in the progress notes must reflect medical necessity, and be available on request.

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Routine use of flow cytometry in situations where the test is performed on tissue or tumor tissue, is not covered. Documentation in the patient's record must demonstrate how the results would impact the treatment plan.

Acute leukemia: Up to 20 antibodies may be required to adequately characterize acute leukemia.

Chronic lymphoproliferative disorder (CLD): Up to 18 antibodies may be required to adequately characterize CLD.

Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.

Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame does not provide any additional information and therefore would be considered not medically necessary.

Flow cytometry used as part of experimental protocols is not a covered service.

This is a revision of policies PATH 96-04 in Minnesota and PATH 016 in Wisconsin. It is a new policy for Illinois and Michigan.

Comments

- Terms:

  ploidy: The number of single sets of chromosomes in a cell or organism.
  diploid: Having two sets or a pair of chromosomes as normally found in the somatic cell of higher organisms. A diploid cell has one chromosome from each parent.
  triploid: Having three times the haploid number of chromosomes in the cell nucleus and would be abnormal in humans.

  aneuploid: Having a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploid cell would be considered abnormal. A triploid cell would be an example of aneuploidy in humans.

- Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.

Sources of Information and Basis for Decision back to top

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Updated on 05/04/2004 with effective dates 11/15/2003 - N/A

Read the LCD Disclaimer

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Exhibit 9

LCD for FLOW CYTOMETRY (L16832)

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00953

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Carrier

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FLOW CYTOMETRY

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Exhibit 9

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CMS National Coverage Policy back to top

TItle XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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Description

Flow Cytometry is a cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. Data is generated and organized by the instrument. Clinical analysis and interpretations are performed by an experienced physician, usually a hemopathologist.

- Immunophenotyping (88180) Flow cytometry; each cell surface marker

  Immunophenotyping is indicated for the following conditions:

  - **HIV infection**

    The status of an HIV-infected patient can be monitored by the analysis of the surface antigen CD4 and CD8. This information can contribute to a prognosis as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem or therapy change, it may be necessary to perform the test at an increased frequency.

    Note: In addition to flow cytometry other tests are used to evaluate and follow this disease such as: T-cell; total count (86359) and or T cell absolute CD4 and CD8 count including ration (86360). On initial evaluation, additional T cell markers may be indicated.

  - **Drug monitoring**

    Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. (Examples of 2 drugs that would fit into this category are Alefacept and Alemtuzamab)

  - **Leukemia or Lymphoma**

    Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Sometimes, flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an antibody panel for appropriate differential diagnosis and classification. This process is sometimes necessary at the initial diagnostic phase, for separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either denovo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen can usually distinguish between potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has already established a diagnosis, and where the neoplastic cells have a characteristic phenotype, may be unnecessary to extensively re-phenotype the lesion; instead, using a limited analysis that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach is probably not appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse are not uncommon.

Leukemia:

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal B lymphocytosis. It can also define certain atypical gains and losses of T cell related antigens that are associated with clonal T cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple "pan" cell and T cell differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T or B cell leukemias.

In the situation of plasma cell dyscrasias (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T or B lineage. For the B cell lineage certain differentiation antigens are prognostically useful.

The acute leukemic panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

Lymphoma

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test and is not always necessary in the diagnosis and staging of every lymphoma. However some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy

(FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panel of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complimentary approaches. The first and newest is to use well-defined panels of 10-12 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical co-expression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell dyscrasia (e.g. plasma cytoma) a smaller panel directed at both cell surface, immunoglobulin light chains and cytoplasmic immunoglobulin light chains, would be appropriate.

Flow cytometry can help define NK cell lineage is rare neoplastic NK proliferations. However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist.

The panel would be performed in stages and may include up to 18 antibodies for lymphomas.

- **Transplants:**

Organ Transplants:

Postoperative monitoring of organ transplants may be necessary to determine early

rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection. The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Stem cell transplants:

To measure CD34 stem cell counts (e.g., CD34, CD45) in patients undergoing autologous transplantation.

- **Primary Immunodeficiencies**

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation.

- **Paroxysmal nocturnal hemoglobinuria**

Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing the red and white blood cells by flow cytometry for the absence of these antigens. In general staining the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and with antibodies to some of the missing antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

- **Hereditary persistence of fetal hemoglobin (HPFH)**

Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modify the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

- **Hereditary Spherocytosis**

  A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

- **HLA B27**

  An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay (86812) that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure.

- DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase) (88182) Flow cytometry; cell cycle or DNA analysis.

- **Carcinomas**

  DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are:

  Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

  Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize.

It has not been proven that this testing provides useful information in colorectal or breast cancers.

This is usually performed only one time after a diagnosis has been made and before treatment is initiated.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:

- Prostatic adenocarcinoma
- Urinary Bladder Carcinoma
- Ovarian Carcinoma
- Endometrial adenocarcinoma
- Renal cell adenocarcinoma
- Mediastinal neuroblastoma
- Medulloblastoma

- **Molar Pregnancies**
  Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles which are triploid can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

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Lab Services

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Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x	Not Applicable

Revenue Codes: back to top

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally

to all Revenue Codes.

99999	Not Applicable

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88180	FLOW CYTOMETRY; EACH CELL SURFACE, CYTOPLASMIC OR NUCLEAR MARKER
88182	FLOW CYTOMETRY; CELL CYCLE OR DNA ANALYSIS
88184	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; FIRST MARKER
88185	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; EACH ADDITIONAL MARKER (LIST SEPARATELY IN ADDITION TO CODE FOR FIRST MARKER)
88187	FLOW CYTOMETRY, INTERPRETATION; 2 TO 8 MARKERS
88188	FLOW CYTOMETRY, INTERPRETATION; 9 TO 15 MARKERS
88189	FLOW CYTOMETRY, INTERPRETATION; 16 OR MORE MARKERS

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CPT codes 88184-88189 are indicated for the following conditions:
(88180-Flow cytometry; each cell surface marker was deleted effective 12/31/2004)

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
079.51	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE I [HTLV-I]
079.52	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE II [HTLV-II]
079.53	HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 [HIV-2]
099.3	REITER'S DISEASE
200.00 - 203.81	RETICULOSARCOMA UNSPECIFIED SITE - OTHER IMMUNOPROLIFERATIVE NEOPLASMS IN REMISSION
204.00	LYMPHOID LEUKEMIA ACUTE WITHOUT REMISSION
204.10	LYMPHOID LEUKEMIA CHRONIC WITHOUT REMISSION
204.20	LYMPHOID LEUKEMIA SUBACUTE WITHOUT REMISSION
204.80	OTHER LYMPHOID LEUKEMIA WITHOUT REMISSION
204.90	UNSPECIFIED LYMPHOID LEUKEMIA WITHOUT REMISSION
205.00	MYELOID LEUKEMIA ACUTE WITHOUT REMISSION
205.10	MYELOID LEUKEMIA CHRONIC WITHOUT REMISSION
205.20	MYELOID LEUKEMIA SUBACUTE WITHOUT REMISSION

205.30	MYELOID SARCOMA WITHOUT REMISSION
205.80	OTHER MYELOID LEUKEMIA WITHOUT REMISSION
205.90	UNSPECIFIED MYELOID LEUKEMIA WITHOUT REMISSION
206.00	MONOCYTIC LEUKEMIA ACUTE WITHOUT REMISSION
206.10	MONOCYTIC LEUKEMIA CHRONIC WITHOUT REMISSION
206.20	MONOCYTIC LEUKEMIA SUBACUTE WITHOUT REMISSION
206.80	OTHER MONOCYTIC LEUKEMIA WITHOUT REMISSION
206.90	UNSPECIFIED MONOCYTIC LEUKEMIA WITHOUT REMISSION
207.00	ACUTE ERYTHREMIA AND ERYTHROLEUKEMIA WITHOUT REMISSION
207.10	CHRONIC ERYTHREMIA WITHOUT REMISSION
207.20	MEGAKARYOCYTIC LEUKEMIA WITHOUT REMISSION
207.80	OTHER SPECIFIED LEUKEMIA WITHOUT REMISSION
208.00	LEUKEMIA OF UNSPECIFIED CELL TYPE ACUTE WITHOUT REMISSION
208.10	LEUKEMIA OF UNSPECIFIED CELL TYPE CHRONIC WITHOUT REMISSION
208.20	LEUKEMIA OF UNSPECIFIED CELL TYPE SUBACUTE WITHOUT REMISSION
208.80	OTHER LEUKEMIA OF UNSPECIFIED CELL TYPE WITHOUT REMISSION
208.90	UNSPECIFIED LEUKEMIA WITHOUT REMISSION
238.6	NEOPLASM OF UNCERTAIN BEHAVIOR OF PLASMA CELLS
238.7	NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
273.1	MONOCLONAL PARAPROTEINEMIA
273.3	MACROGLOBULINEMIA
279.10 - 279.9	IMMUNODEFICIENCY WITH PREDOMINANT T-CELL DEFECT UNSPECIFIED - UNSPECIFIED DISORDER OF IMMUNE MECHANISM
282.0	HEREDITARY SPHEROCYTOSIS
282.5	SICKLE-CELL TRAIT
282.60 - 282.69	SICKLE-CELL DISEASE UNSPECIFIED - OTHER SICKLE-CELL DISEASE WITH CRISIS
282.7	OTHER HEMOGLOBINOPATHIES
283.2	HEMOGLOBINURIA DUE TO HEMOLYSIS FROM EXTERNAL CAUSES
288.0 - 288.9	AGRANULOCYTOSIS - UNSPECIFIED DISEASE OF WHITE BLOOD CELLS
334.8	OTHER SPINOCEREBELLAR DISEASES
364.3	UNSPECIFIED IRIDOCYCLITIS
555.0 - 556.9	REGIONAL ENTERITIS OF SMALL INTESTINE - ULCERATIVE COLITIS UNSPECIFIED
696.0	PSORIATIC ARTHROPATHY

714.30	CHRONIC OR UNSPECIFIED POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS
720.0 - 720.9	ANKYLOSING SPONDYLITIS - UNSPECIFIED INFLAMMATORY SPONDYLOPATHY
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630	HYDATIDIFORM MOLE

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N/A

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N/A

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Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.

Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame does not provide any additional information and therefore would be considered not medically necessary.

Flow cytometry used as part of experimental protocols is not a covered service.

This is a revision of policies PATH 96-04 in Minnesota and PATH 016 in Wisconsin. It is a new policy for

Illinois and Michigan.

Comments

- Terms:

  ploidy: The number of single sets of chromosomes in a cell or organism.
  diploid: Having two sets or a pair of chromosomes as normally found in the somatic cell of higher organisms. A diploid cell has one chromosome from each parent.
  triploid: Having three times the haploid number of chromosomes in the cell nucleus and would be abnormal in humans.

  aneuploid: Having a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploid cell would be considered abnormal. A triploid cell would be an example of aneuploidy in humans.

- Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.

Sources of Information and Basis for Decision back to top

CLIC-AAAAI, Practice Parameters for the Diagnosis and Management of Immunodeficiency, *Annals of Allergy, Asthma, & Immunology*, August 31, 1995, pp 282-294

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11/18/2004

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There are no attachments for this LCD.

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Updated on 03/30/2005 with effective dates 01/01/2005 - N/A

Updated on 05/04/2004 with effective dates 11/15/2003 - N/A

Read the LCD Disclaimer

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Exhibit 10

Medicare Coverage Database

LCD for FLOW CYTOMETRY (L16833)

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Wisconsin Physicians Service Insurance Corporation

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00954

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Carrier

LCD Information

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L16833

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FLOW CYTOMETRY

Contractor's Determination Number back to top

PATH-016

Exhibit 10

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Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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Indications and Limitations of Coverage and/or Medical Necessity back to top

Description

Flow Cytometry is a cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. Data is generated and organized by the instrument. Clinical analysis and interpretations are performed by an experienced physician, usually a hemopathologist.

- Immunophenotyping (88180) Flow cytometry; each cell surface marker

  Immunophenotyping is indicated for the following conditions:

  - **HIV Infection**

    The status of an HIV-infected patient can be monitored by the analysis of the surface antigen CD4 and CD8. This information can contribute to a prognosis as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem or therapy change, it may be necessary to perform the test at an increased frequency.

    Note: In addition to flow cytometry other tests are used to evaluate and follow this disease such as: T-cell; total count (86359) and or T cell absolute CD4 and CD8 count including ration (86360). On initial evaluation, additional T cell markers may be indicated.

  - **Drug monitoring**

    Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. (Examples of 2 drugs that would fit into this category are Alefacept and Alemtuzamab)

  - **Leukemia or Lymphoma**

    Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Sometimes, flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an antibody panel for appropriate differential diagnosis and classification. This process is sometimes necessary at the initial diagnostic phase, for separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either denovo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen can usually distinguish between potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has already established a diagnosis, and where the neoplastic cells have a characteristic phenotype, may be unnecessary to extensively re-phenotype the lesion; instead, using a limited analysis that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach is probably not appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse are not uncommon.

Leukemia:

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal B lymphocytosis. It can also define certain atypical gains and losses of T cell related antigens that are associated with clonal T cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple "pan" cell and T cell differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T or B cell leukemias.

In the situation of plasma cell dyscrasias (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T or B lineage. For the B cell lineage certain differentiation antigens are prognostically useful.

The acute leukemic panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

Lymphoma

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test and is not always necessary in the diagnosis and staging of every lymphoma. However some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy

(FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panel of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complimentary approaches. The first and newest is to use well-defined panels of 10-12 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical co-expression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell dyscrasia (e.g. plasma cytoma) a smaller panel directed at both cell surface, immunoglobulin light chains and cytoplasmic immunoglobulin light chains, would be appropriate.

Flow cytometry can help define NK cell lineage is rare neoplastic NK proliferations. However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist.

The panel would be performed in stages and may include up to 18 antibodies for lymphomas.

- **Transplants:**

Organ Transplants:

Postoperative monitoring of organ transplants may be necessary to determine early

rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection. The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Stem cell transplants:

To measure CD34 stem cell counts (e.g., CD34, CD45) in patients undergoing autologous transplantation.

- **Primary Immunodeficiencies**

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation.

- **Paroxysmal nocturnal hemoglobinuria**

Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing the red and white blood cells by flow cytometry for the absence of these antigens. In general staining the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and with antibodies to some of the missing antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

- **Hereditary persistence of fetal hemoglobin (HPFH)**

Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modify the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

- **Hereditary Spherocytosis**

  A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

- **HLA B27**

  An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay (86812) that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure.

- DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase) (88182) Flow cytometry; cell cycle or DNA analysis.

- **Carcinomas**

  DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are:

  Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

  Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize.

It has not been proven that this testing provides useful information in colorectal or breast cancers.

This is usually performed only one time after a diagnosis has been made and before treatment is initiated.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:

- Prostatic adenocarcinoma
- Urinary Bladder Carcinoma
- Ovarian Carcinoma
- Endometrial adenocarcinoma
- Renal cell adenocarcinoma
- Mediastinal neuroblastoma
- Medulloblastoma

- **Molar Pregnancies**
  Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles which are triploid can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

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Lab Services

Coding Information

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Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x	Not Applicable

Revenue Codes: back to top

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally

to all Revenue Codes.

99999	Not Applicable

CPT/HCPCS Codes back to top

88180	FLOW CYTOMETRY; EACH CELL SURFACE, CYTOPLASMIC OR NUCLEAR MARKER
88182	FLOW CYTOMETRY; CELL CYCLE OR DNA ANALYSIS
88184	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; FIRST MARKER
88185	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; EACH ADDITIONAL MARKER (LIST SEPARATELY IN ADDITION TO CODE FOR FIRST MARKER)
88187	FLOW CYTOMETRY, INTERPRETATION; 2 TO 8 MARKERS
88188	FLOW CYTOMETRY, INTERPRETATION; 9 TO 15 MARKERS
88189	FLOW CYTOMETRY, INTERPRETATION; 16 OR MORE MARKERS

ICD-9 Codes that Support Medical Necessity back to top

CPT codes 88184-88189 are indicated for the following conditions:
(88180-Flow cytometry; each cell surface marker was deleted effective 12/31/2004)

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
079.51	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE I [HTLV-I]
079.52	HUMAN T-CELL LYMPHOTROPHIC VIRUS TYPE II [HTLV-II]
079.53	HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 [HIV-2]
099.3	REITER'S DISEASE
200.00 - 203.81	RETICULOSARCOMA UNSPECIFIED SITE - OTHER IMMUNOPROLIFERATIVE NEOPLASMS IN REMISSION
204.00	LYMPHOID LEUKEMIA ACUTE WITHOUT REMISSION
204.10	LYMPHOID LEUKEMIA CHRONIC WITHOUT REMISSION
204.20	LYMPHOID LEUKEMIA SUBACUTE WITHOUT REMISSION
204.80	OTHER LYMPHOID LEUKEMIA WITHOUT REMISSION
204.90	UNSPECIFIED LYMPHOID LEUKEMIA WITHOUT REMISSION
205.00	MYELOID LEUKEMIA ACUTE WITHOUT REMISSION
205.10	MYELOID LEUKEMIA CHRONIC WITHOUT REMISSION
205.20	MYELOID LEUKEMIA SUBACUTE WITHOUT REMISSION

205.30	MYELOID SARCOMA WITHOUT REMISSION
205.80	OTHER MYELOID LEUKEMIA WITHOUT REMISSION
205.90	UNSPECIFIED MYELOID LEUKEMIA WITHOUT REMISSION
206.00	MONOCYTIC LEUKEMIA ACUTE WITHOUT REMISSION
206.10	MONOCYTIC LEUKEMIA CHRONIC WITHOUT REMISSION
206.20	MONOCYTIC LEUKEMIA SUBACUTE WITHOUT REMISSION
206.80	OTHER MONOCYTIC LEUKEMIA WITHOUT REMISSION
206.90	UNSPECIFIED MONOCYTIC LEUKEMIA WITHOUT REMISSION
207.00	ACUTE ERYTHREMIA AND ERYTHROLEUKEMIA WITHOUT REMISSION
207.10	CHRONIC ERYTHREMIA WITHOUT REMISSION
207.20	MEGAKARYOCYTIC LEUKEMIA WITHOUT REMISSION
207.80	OTHER SPECIFIED LEUKEMIA WITHOUT REMISSION
208.00	LEUKEMIA OF UNSPECIFIED CELL TYPE ACUTE WITHOUT REMISSION
208.10	LEUKEMIA OF UNSPECIFIED CELL TYPE CHRONIC WITHOUT REMISSION
208.20	LEUKEMIA OF UNSPECIFIED CELL TYPE SUBACUTE WITHOUT REMISSION
208.80	OTHER LEUKEMIA OF UNSPECIFIED CELL TYPE WITHOUT REMISSION
208.90	UNSPECIFIED LEUKEMIA WITHOUT REMISSION
238.6	NEOPLASM OF UNCERTAIN BEHAVIOR OF PLASMA CELLS
238.7	NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
273.1	MONOCLONAL PARAPROTEINEMIA
273.3	MACROGLOBULINEMIA
279.10 - 279.9	IMMUNODEFICIENCY WITH PREDOMINANT T-CELL DEFECT UNSPECIFIED - UNSPECIFIED DISORDER OF IMMUNE MECHANISM
282.0	HEREDITARY SPHEROCYTOSIS
282.5	SICKLE-CELL TRAIT
282.60 - 282.69	SICKLE-CELL DISEASE UNSPECIFIED - OTHER SICKLE-CELL DISEASE WITH CRISIS
282.7	OTHER HEMOGLOBINOPATHIES
283.2	HEMOGLOBINURIA DUE TO HEMOLYSIS FROM EXTERNAL CAUSES
288.0 - 288.9	AGRANULOCYTOSIS - UNSPECIFIED DISEASE OF WHITE BLOOD CELLS
334.8	OTHER SPINOCEREBELLAR DISEASES
364.3	UNSPECIFIED IRIDOCYCLITIS
555.0 - 556.9	REGIONAL ENTERITIS OF SMALL INTESTINE - ULCERATIVE COLITIS UNSPECIFIED
696.0	PSORIATIC ARTHROPATHY

714.30	CHRONIC OR UNSPECIFIED POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS
720.0 - 720.9	ANKYLOSING SPONDYLITIS - UNSPECIFIED INFLAMMATORY SPONDYLOPATHY
795.4	OTHER NONSPECIFIC ABNORMAL HISTOLOGICAL FINDINGS
996.80 - 996.89	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN
V42.0 - V42.89	KIDNEY REPLACED BY TRANSPLANT - OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS

CPT code 88182 (Flow cytometry; cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:

164.2	MALIGNANT NEOPLASM OF ANTERIOR MEDIASTINUM
164.3	MALIGNANT NEOPLASM OF POSTERIOR MEDIASTINUM
182.0	MALIGNANT NEOPLASM OF CORPUS UTERI EXCEPT ISTHMUS
183.0	MALIGNANT NEOPLASM OF OVARY
183.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF UTERINE ADNEXA
185	MALIGNANT NEOPLASM OF PROSTATE
188.0 - 188.9	MALIGNANT NEOPLASM OF TRIGONE OF URINARY BLADDER - MALIGNANT NEOPLASM OF BLADDER PART UNSPECIFIED
189.0	MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS
189.1	MALIGNANT NEOPLASM OF RENAL PELVIS
191.0 - 191.8	MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES - MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN
630	HYDATIDIFORM MOLE

Diagnoses that Support Medical Necessity back to top

N/A

ICD-9 Codes that DO NOT Support Medical Necessity back to top

N/A

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation back to top

Diagnoses that DO NOT Support Medical Necessity back to top

N/A

General Information

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Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

Documentation in the progress notes must reflect medical necessity, and be available on request.

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Routine use of flow cytometry in situations where the test is performed on tissue or tumor tissue, is not covered. Documentation in the patient's record must demonstrate how the results would impact the treatment plan.

Acute leukemia: Up to 20 antibodies may be required to adequately characterize acute leukemia.

Chronic lymphoproliferative disorder (CLD): Up to 18 antibodies may be required to adequately characterize CLD.

Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.

Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame does not provide any additional information and therefore would be considered not medically necessary.

Flow cytometry used as part of experimental protocols is not a covered service.

This is a revision of policies PATH 96-04 in Minnesota and PATH 016 in Wisconsin. It is a new policy for

Illinois and Michigan.

Comments

- Terms:

  ploidy: The number of single sets of chromosomes in a cell or organism.
  diploid: Having two sets or a pair of chromosomes as normally found in the somatic cell of higher organisms. A diploid cell has one chromosome from each parent.
  triploid: Having three times the haploid number of chromosomes in the cell nucleus and would be abnormal In humans.

  aneuploid: Having a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploid cell would be considered abnormal. A triploid cell would be an example of aneuploidy in humans.

- Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.

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CLIC-AAAAI, Practice Parameters for the Diagnosis and Management of Immunodeficiency, *Annals of Allergy, Asthma, & Immunology*, August 31, 1995, pp 282-294

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Fukunaga, M., Early partial hydatidiform mole: prevalence, histopathology, DNA ploidy, and persistence rate. Virchows Arch, 2000. 437(2): p. 180-4.

Fukunaga, M., Flow cytometric and clinicopathologic study of complete hydatidiform moles with special reference to the significance of cytometric aneuploidy. Gynecol Oncol, 2001. 81(1): p. 67-70.

Braylan, R.C., et al., U.S.-Canadian Consensus recommendations on the immunophenotypic analysis of hematologic neoplasia by flow cytometry: data reporting. Cytometry, 1997. 30(5): p. 245-8.

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Other Carrier policies

Advisory Committee Meeting Notes back to top

05/08/2003

Start Date of Comment Period back to top

05/28/2003

End Date of Comment Period back to top

07/15/2003

Start Date of Notice Period back to top

07/01/2005

Revision History Number back to top

Revision History Explanation back to top

ICD-9 code added

Last Reviewed On Date back to top

11/18/2004

Related Documents back to top

This LCD has no Related Documents.

LCD Attachments back to top

There are no attachments for this LCD.

Other Versions back to top

Updated on 03/30/2005 with effective dates 01/01/2005 - N/A

Updated on 05/04/2004 with effective dates 11/15/2003 - 12/31/2004

Read the LCD Disclaimer

Exhibit 11

James T. O'Neill
235 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

September 22, 2005

Ms. Monica Perkins
CMS, Chicago Regional Office
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601

RE: FOIA Request

Dear Ms. Perkins:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. The "Advisory Committee Meeting Notes" related to Local Coverage Determinations Nos. L16830 through L16834. (Note: These LCDs themselves contain the following relevant information: "Advisory Committee Meeting Notes 5/28/2003").

I agree in advance to pay fees of up to $200 without further consultation or approval. If CMS anticipates that charges will exceed $200, please contact me before exceeding this figure.

I will be happy to discuss with the agency possibly ways to reduce the scope and burden of the request. For example, LCDs L16830 through L16833 appear to be essentially the same document, with the sole difference between them being that they apply to different states. If there are four sets of records that are identical save for references to different states, there may be places where can cut down the paper involved by three-quarters.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

Exhibit
11

Exhibit 12

James T. O'Neill
325 West Huron Street
Suite 230
Chicago. Illinois 60610
(312) 654-8685

September 22, 2005

Ms. Monica Perkins
CMS, Chicago Regional Office
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601

RE: FOIA Request

Dear Ms. Perkins:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. All records concerning the adoption by the Wisconsin Physicians Service Insurance Corporation of Local Coverage Determinations L16830, L16831, L16832, and L16833. (Note: These LCDs concern "Flow Cytometry.")

This request includes (without limiting its scope):

(a) all comments received by WPSIC regarding any interim or final LCD for Flow Ctytometry that preceded L16830-33;

(b) all records of communications between WPSIC and public commenters regarding the development of L16830-16833, including notes or other records of oral communications;

(c) all communications between WPSIC and CMS or HCFA regarding the consideration or adoption of L16830-16833; and

(d) all internal WPSIC documents reflecting the considerations that led to the adoption of L16830-33.

I agree in advance to pay fees of up to $350 without further consultation or approval. If CMS anticipates that charges will exceed $350, please contact me before exceeding this figure.

I don't know exactly what kind of records WPSIC and/or CMS may maintain regarding the adoption of LCDs L16830-16833. For this reason, this request may be broader than it ultimately needs to be. I'm always happy to discuss with the agency possibly ways to reduce the scope and burden of the request.

Exhibit 12

For example, LCDs L16830 through L16833 appear to be essentially the same document, with the sole difference between them being that they apply to different states. If there are four sets of records that are identical save for references to different states, there may be places where can cut down the paper involved by three-quarters.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

Exhibit 13

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

P.O. Box 4433
Marion, IL 62959

November 17, 2005

James T. O'Neill
235 West Huron Street
Suite 230
Chicago, IL 60610

Dear Mr. O'Neill:

This is in response to your Freedom of Information Act (FOIA) request for Advisory committee Meeting Notes related to Local Coverage Determination L16830 through L16834. Your request has been assigned FOI Case No. 5509521698.

The Freedom of Information Act provides that a requester may ask for existing records or documents. This means we cannot analyze or interpret the information we release.

Records/documents from one or more of the following sources are provided in response to your request:

/ CMS Manual System: Policy Path-016; Final Comments for Path-016

_____ Other: Duplicate Medicare Summary Notices, multiple dates of service.

Sincerely,

Freedom of Information
Government Contracts Division
Medicare B

Exhibit
13

Contractor Name
Wisconsin Physicians Service (WPS)

Contractor Number
00951, 00952, 00953, 00954

Contractor Type
Carrier

LCD Database ID Number

LCD Version Number

LCD Title
Flow Cytometry

Contractor's Determination Number
PATH-016

AMA CPT/ ADA CDT Copyright Statement

CMS National Coverage Policy
Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Primary Geographic Jurisdiction
Wisconsin, Illinois, Michigan, Minnesota

Oversight Region
Region V

CMS Consortium
Midwest

Original Policy Effective Date

Wisconsin:	09/01/95; 11/15/2003
Illinois:	11/15/2003
Michigan:	11/15/2003
Minnesota:	03/01/97; 01/01/01; 11/15/2003

Revision Effective Date
01/01/2005

Indications and Limitations of Coverage and/or Medical Necessity
Description

Flow Cytometry is a cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. Data is generated and organized by the instrument. Clinical analysis and interpretations are performed by an experienced physician, usually a hemopathologist.

A. Immunophenotyping:

The cells of the immune system bear on their surfaces and within their cytoplasm or nucleus hundreds of molecules specific for their particular developmental stage and functional state. There have been more than 260 types of molecules identified on the surface of human leukocytes but only around 30 of these are associated with a known structure or function.

The process of measuring the types of antigens expressed on and within a cell by flow cytometry is referred to as immunophenotyping. To detect these antigens, antigen-specific monoclonal antibodies are used which have been labeled with a fluorescent dye or fluorochrome. After washing away any unbound antibody, the cells are analyzed by flow cytometry which categorizes them by size, granularity and fluorochrome intensity. An international standard nomenclature is used to categorize most antibodies according to the antigens they detect. Each category is called a cluster of differentiation (CD) and is numbered. A few clinically useful antibodies have not yet been "clustered" and are referred to by names derived from site of origin or nomenclature used in other classification systems (e.g. histocompatibility and immunoglobulin antigens).

DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase)

1. Malignant cells sometimes show abnormalities in total chromosome number and the frequency of these abnormalities generally increases with progression to higher-grade tumors.
   Flow cytometric methods can be used to measure nuclear deoxyribonucleic acid (DNA) content (ploidy) as a prognostic indicator of solid tumors. Fluorescent dyes are used to stain nucleic acids. DNA diploid tumors are those where a single peak containing an amount of DNA similar to normal cells is generated by flow cytometry. DNA aneuploid tumors have additional peaks on the DNA histogram which may represent cells containing more or less nucleic acid found in 46 normal chromosomes.
   A more quantitative method of expression is the DNA index (DI), which is the ratio of the mean tumor sample G0/G1 DNA content divided by the mean G0/G1 DNA content of normal diploid reference cells. The greater the deviation of the DI from 1, the more "aneuploid" the tumor.

2. The assessment of % S-phase or the S phase fraction (SPF) measures the percentage or proportion of cells preparing for mitosis by their active doubling of DNA. Tumor cells tend to replicate more readily than normal cells therefore increased SPF activity can raise the question of malignancy. Frequently a high SPF will correlate positively with poor differentiation, increasing tumor size and degree of aggressiveness.

Indications and Limitations of Coverage and/or Medical Necessity

The specimen analysis is dependent on the diagnosis of the patient.

A. Immunophenotyping (88184-88189) is indicated for the following conditions:

1. **HIV infection**
   The status of an HIV-infected patient can be monitored by the analysis of the surface antigen CD4 and CD8. This information can contribute to a prognosis as well as medical management for

that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem or therapy change, it may be necessary to perform the test at an increased frequency.
Note: In addition to flow cytometry other tests are used to evaluate and follow this disease such as: T cell; total count (86359) and or T cell absolute CD4 and CD8 count including ratio (86360). On initial evaluation, additional T cell markers may be indicated.

2. **Drug monitoring**
Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. (Examples of 2 drugs that would fit into this category are Alefacept and Alemtuzamab)

3. **Leukemia or Lymphoma**
Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Sometimes, flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an antibody panel for appropriate differential diagnosis and classification. This process is sometimes necessary at the initial diagnostic phase, for separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either denovo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen can usually distinguish between potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has already established a diagnosis, and where the neoplastic cells have a characteristic phenotype, may be unnecessary to extensively re-phenotype the lesion; instead, using a limited analysis that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach is probably not appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse are not uncommon.

Leukemia:
Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal B lymphocytosis. It can also define certain atypical gains and losses of T cell related antigens that are associated with clonal T cell lymphoproliferations.
At a minimum, flow cytometric analysis for mature B cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple "pan" cell and T cell differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T or B cell leukemias. In the situation of plasma cell dyscrasias (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute

leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T or B lineage. For the B cell lineage certain differentiation antigens are prognostically useful.
The acute leukemic panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

Lymphoma
An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test and is not always necessary in the diagnosis and staging of every lymphoma. However some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy (FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.
The panel of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.
For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.
For T cell proliferations, clonality can usually be assessed using two complimentary approaches. The first and newest is to use well-defined panels of 10-12 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical co-expression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell dyscrasia (e.g. plasma cytoma) a smaller panel directed at both cell surface, immunoglobulin light chains and cytoplasmic immunoglobulin light chains, would be appropriate.
Flow cytometry can help define NK cell lineage is rare neoplastic NK proliferations. However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist.
The panel would be performed in stages and may include up to 18 antibodies for lymphomas.

3. **Transplants:**
Organ Transplants:
Postoperative monitoring of organ transplants may be necessary to determine early rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection. The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient.

Stem cell transplants:
To measure stem cell counts (e.g. CD34, CD45) in patients undergoing autologous transplantation.

4. **Primary Immunodeficiencies**
Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC, platelet, WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation.

5. **Paroxysmal Nocturnal Hemoglobinuria**
Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing the red and white blood cells by flow cytometry for the absence of these antigens. In general staining the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and with antibodies to some of the missing antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis.

6. **Hereditary Persistence of Fetal Hemoglobin (HPFH)**
Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modify the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

7. **Hereditary Spherocytosis**
A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the

dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

8. **HLA B27**
An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay (86812) that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure.

B. DNA content (ploidy) and cell proliferative activity (S-phase fraction or %S-phase) (88182) Flow cytometry; cell cycle or DNA analysis.

1. **Carcinomas**
DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are: Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.
Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize.
It has not been proven that this testing provides useful information in colorectal or breast cancers.
This is usually performed only one time after a diagnosis has been made and before treatment is initiated.
This testing is indicated for selected patients (without metastatic disease) with the following conditions:
   a. Prostatic adenocarcinoma
   b. Urinary Bladder Carcinoma
   c. Ovarian Carcinoma
   d. Endometrial adenocarcinoma
   e. Renal cell adenocarcinoma
   f. Mediastinal neuroblastoma
   g. Medulloblastoma

2. **Molar Pregnancies**
Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles, which are triploid, can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.

Coverage Topic
Pathology and Laboratory

CPT/HCPCS Codes

88180	Flow cytometry; each cell surface marker (deleted effective after 12/31/2004)
88182	Flow cytometry; cell cycle or DNA analysis
88184	Flow cytometry, cell surface, cytoplasmic or nuclear marker, technical component only; first marker
88185	------, technical component only; each additional marker (list separately in addition to code for first marker
88187	Flow cytometry, interpretation; 2 to 8 markers
88188	------, interpretation; 9 to15 markers
88189	------, interpretation; 16 or more markers

Does the CPT 30% Rule Apply

No

ICD-9 Codes that Support Medical Necessity

A. CPT codes 88184-88189 are indicated for the following conditions:
(88180-Flow cytometry; each cell surface marker was deleted effective 12/31/2004)

1. HIV infection (ICD-9 042, 079.51, 079.52, 079.53), as defined by the Center for Disease Control criteria.
2. Leukemias (ICD-9 204.00-208.91)
3. Lymphomas (ICD-9 200.00-203.81)
*4. Abnormal tissue, bone marrow, or blood histology when the results are suspicious for lymphoma or leukemia and where the physician must distinguish reactive from neoplastic conditions (ICD-9 238.6, *238.7, 795.4).
5. Postoperative monitoring of organ transplant patients (ICD-9 996.80-996.89, V42.0-V42.89).
6. Pretransplant evaluation of allogenic or autologous donor cells (V42.82)
7. Primary immunodeficiencies (ICD-9 279.10-279.9, 288.0-288.9, 334.8)
8. Monoclonal gammopathies (ICD-9 273.1, 273.3)
9. Certain hemolytic anemias:
Paroxysmal nocturnal hemoglobinuria (ICD-9 283.2)
Hereditary spherocytosis (ICD-9 282.0)
Sickle cell (ICD-9 282.5, 282.60-282.69)
HPFH (ICD-9 282.7)
10. Drug monitoring (ICD-9 V58.69)
11. Conditions associated with gene HLA B27
Reiter's syndrome (ICD-9 099.3)
Uveitis (ICD-9 364.3)
Psoriatic arthritis (ICD-9 696.0)
Juvenile arthritis (ICD-9 714.30)
Ankylosing spondylitis (ICD-9 720.0-720.9)
Inflammatory bowel disease (ICD-9 555.0-556.9)

B. CPT code 88182 (Flow cytometry; cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:
1. Prostatic adenocarcinoma (ICD-9 185)
2. Urinary Bladder Carcinoma (ICD-9 188.0-188.9)
3. Ovarian Carcinoma (ICD-9 183.0, 183.8)
4. Endometrial adenocarcinoma (ICD-9 182.0)

5. Renal cell adenocarcinoma (ICD-9 189.0, 189.1)
6. Mediastinal neuroblastoma (ICD-9 164.2, 164.3)
7. Medulloblastoma (ICD-9 191.0-191.8)
8. Molar pregnancy (ICD-9 630)

Note: ICD-9 codes must be coded to the highest level of specificity.

Diagnoses that Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Documentation Requirements
Documentation supporting the medical necessity of this item, such as ICD-9 codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

Documentation in the progress notes and/or in the pathology report(s) must reflect medical necessity, and be available on request.

Utilization Guidelines
Routine use of flow cytometry in situations where the test is performed on tissue or tumor tissue is not covered. Documentation in the patient's record must demonstrate how the results would impact the treatment plan.

Acute leukemia: Up to 20 antibodies may be required to adequately characterize acute leukemia.
Chronic lymphoproliferative disorder (CLD): Up to 18 antibodies may be required to adequately characterize CLD.

Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.

Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame does not provide any additional information and therefore would be considered not medically necessary.

Flow cytometry used as part of experimental protocols is not a covered service.

Comments

A. Terms:

ploidy:	The number of single sets of chromosomes in a cell or organism.
diploid:	Having two sets or a pair of chromosomes as normally found in the somatic cell of higher organisms. A diploid cell has one chromosome from each parent.
triploid:	Having three times the haploid number of chromosomes in the cell nucleus and would be abnormal in humans.
aneuploid:	Having a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploid cell would be considered abnormal. A triploid cell would be an example of aneuploidy in humans.

B. Flow cytometry is a dynamic field. We will evaluate any requests for extension of coverage that are supported by peer-reviewed literature.

Sources of Information and Basis for Decision

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Wright, et, al, A Characterization of Common Variable Immunodeficiency: Identification of a Subset of Patients with Distinctive Immunophenotypic and Clinical Features, *Blood*, Vol 76, No. 10 (November 15), 1990, pp 2046-2051

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Mathews, et, al, A Function of the Interleukin-2 (IL-2) Receptor G-Chain in Biologic Responses of X-Linked Severe Combined Immunodeficient B Cells to IL-2, IL-4, IL-13, and IL-15", *Blood*, Vol 85, No1 (January 1), 1995, pp 38-42

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Braylan, R.C., et al., U.S.-Canadian Consensus recommendations on the immunophenotypic analysis of hematologic neoplasia by flow cytometry: data reporting. *Cytometry*, 1997. 30(5): p. 245-8.

Braylan, R.C., et al., Optimal number of reagents required to evaluate hematolymphoid neoplasias: results of an international consensus meeting. *Cytometry*, 2001. 46(1): p. 23-7.

Hanson, C.A., et al., Immunophenotypic analysis of peripheral blood and bone marrow in the staging of B-cell malignant lymphoma. *Blood*, 1999. 94(11): p. 3889-96.

2000 update on recommendations for the use of tumor markers in breast and colorectal cancer; Clinical Practice Guidelines of the American Society of Clinical Oncology; *J.Clin.Ocol.* 2001; 19(6): 1865-1878

Davis, Bruce H., et al; U.S.- Canadian Consensus Recommendations on Immunophenotypic Analysis of Hematologic Neoplasia by Flow Cytometry: Medical Indications; *Cytometry* 1997 30:249-263

Stewart, Carleton C., et al; U.S. Canadian Consensus Recommendations on the Immunophenotypic Analysis of Hematologic Neoplasia by Flow Cytometry: Selection of Antibody Combinations; *Cytometry* 1997 30: 231-235

Hassett, Joseph; Parker, John; Laboratory Practices in Reporting Flow Cytometry Phenotyping Results for Leukemia/Lymphoma Specimens: Results of Survey; *Cytometry* 1995; 22: 264-281

McCoy, J. Philip; Davis, Bruce; Report of the Clinical Practice Task Force Survey of the Clinical Cytometric Society; *Cytometry* 2001; 46: 177-183

McCoy, J., Philip; Overton, W.R; A survey of Current Practices in Clinical Flow Cytometry, *AJCP* 1996; Vol 106 No.1 82-86

Other Carrier policies

Advisory Committee Notes

Meeting Date:

Wisconsin:	05/16 /2003; 03/24/95
Illinois:	05/28 /2003
Michigan:	05/07/2003
Minnesota:	05/08 /2003; 09/30/96

Start Date of Comment Period

05/28/2003

End Date of Comment Period

07/15/2003

Start Date of Notice Period

(Published)

Wisconsin:	03/10/95; 08/01/95; Article 09/01/96; Article 01/01/97; Article 02/01/98; 10/01/2003; 01/01/2005; Article 04/01/2005; *Article 07/01/2005
Illinois:	10/01/2003; 01/01/2005; Article 04/01/2005; *Article 07/01/2005
Michigan:	10/01/2003; 01/01/2005; Article 04/01/2005; *Article 07/01/2005
Minnesota:	02/01/97; 0/01/2003; 01/01/2005; Article 04/01/2005; *Article 07/01/2005

Revision History

Wisconsin:	08/01/96, one; 10/15/96, two; 01/01/98, three (ICD-9 update); 05/01/2004, LCD reformat; New codes 88184 - 88189 added effective 01/01/2005. 88180 deleted four; 04/01/2005 icd-9 code corrected, five; *Article 07/01/2005, icd-9 code added
Illinois:	05/01/2004, LCD reformat; New codes 88184 - 88189 added effective 01/01/2005. 88180 deleted; 04/01/2005 icd-9 code corrected; *Article 07/01/2005, icd-9 code added
Michigan:	05/01/2004, LCD reformat; New codes 88184 - 88189 added effective 01/01/2005. 88180 deleted; 04/01/2005 icdd-9 code corrected; *Article 07/01/2005, icd-9 code

	added
Minnesota:	10/31/00, one (added ICD-9's); 05/01/2004, LCD reformat; New codes 88184 - 88189 added effective 01/01/2005. 88180 deleted; 04/01/2005 icd-9 code corrected; *Article 07/01/2005, icd-9 code added

This policy does not reflect the sole opinion of the carrier or Carrier Medical Director. This policy was developed considering comments from the medical community via the Carrier Advisory Committee, which includes representatives from all specialties.

Last Reviewed On
11/18/2004

Notes
There is no coding document associated with this policy.

Italicized font - represents CMS national policy language/wording copied directly from CMS Manuals or CMS Transmittals. Carriers are prohibited from changing national policy language/wording. Providers, through their associations/societies, should contact CMS to request changes to national policy through the Medicare Coverage Policy Process at http://www.cms/hhs.gov/coverage

* - An asterisk indicates a revision to that section of the policy.

Does this LCD contain a "Least Costly Alternative" Provision?
No

Wisconsin Physicians Service
Medicare Part B

FINAL COMMENTS for PATH-016

Author

Jen Stanton
Board Administrator
Username: Admin

Post Number: 8
Registered: 10-2002

Message

Posted on Tuesday, November 18, 2003 - 01:27 pm:

1. There were many comments objecting to the following statement.

There is available some logic as to the approach to take in evaluating the need and the extent of flow cytometric tests of leukemia and lymphoma. If the decision is to proceed a triage panel of assays utilizing antibodies to CD45, CD19, kappa and lambda light chains, CD3 and DC 16 are performed. If the results do not reveal any abnormalities and if the clinical and morphological features do not indicate leukemia or lymphoma, additional tests are unnecessary.
If the initial panel indicates a potential B cell lymphoma or B cell lymphoproliferative disorder an additional panel of 8 antibodies are used to characterize the disease process.
If the process reveals an acute leukemia or T-cell lymphoproliferative disorder 7-12 antibodies would be needed in the analysis.

Response:
This logic has been removed from the policy. There currently is no consensus to support this logic. Instead other logic was provided which was used in the policy. This does not mean the pathologist cannot use the above process. The key statement in this regard is:
Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (blood smear, bone marrow smear, and lymph node frozen section) and determines if the lesion is amenable to analysis by flow cytometry.

This would also include the determination of the specific tests needed to assist the physician in diagnosis and treatment.

2. The majority of comments on this policy centered on the number of markers required to assist in the diagnosis and follow-up of leukemia or lymphoma.

Response:
Based on the literature and comments received we have come as close as possible to
the usual number of markers needed and we have made an allowance for more if it is supported in the pathologist's report..

Leukemia:

Acute leukemia: Up to 20 antibodies may be required to adequately characterize acute leukemia.

Chronic lymphoproliferative disorder (CLD): Up to 18 antibodies may be required to adequately characterize CLD.

Lymphoma:

Lymphoma: Up to 18 antibodies may be required to adequately characterize lymphoma.
Plasma cell dyscrasia: Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the flow cytometry narrative report.

3. There was a critique that we were discussing the number of markers needed for specific diseases yet we lacked certain literature that discussed these parameters.

Response:
We have acquired the literature with the help of one of our pathology CAC members and have reviewed it. This helped us come to the decision discussed under NO. 1. The sources have been added to our bibliography.

4. There were suggestions for additional ICD-9 codes.

Response:
We added many of those requested. Some of those requested were not supported by the narrative under indications or limitations of coverage or by the literature available. We did provide a more limited range of codes which will support most uses.

5. There was a comment that other "monoclonal" drugs were currently being utilized or would be developed soon and would need to be monitored.

Response:
We made this section less specific and will cover flow cytometry for monitoring of those drugs that require this type of monitoring.

6. HLA B27 has been added to this final document. While we received no comments on this it was discovered that this was a legitimate newer use of flow cytometry when it replaces the lymphocytotoxicity assay (86812).

Add Your Message Here

Post:

Username:

Password:

Posting Information:
This is a private posting area. Only registered users and moderators may post messages here.

Options: ☑ Automatically activate URLs in message

Action: Preview/Post Message

Administration **Log Out** **Previous Page** **Next Page**

Exhibit 14

FACSIMILE

From: James T. O'Neill
FAX (312) 276-8163 Phone (312) 654-8685

To: Wisconsin Physicians Service (WPS) -- Medicare Part B
Attn: Freedom Of Information Dept.
Fax: (618) 998-5287

Date: December 1, 2005

Total Pages (incl. this cover sheet): ____4____

Message:

RE: FOIA Requests

Two (2) Freedom of Information Act requests enclosed.

One of them (regarding Advisory Committee notes) is nearly identical to a request that Doyce Campbell already is working on. However, the previous request was forwarded by to you CMS-Chicago, and I wanted to make sure I sent a request directly to you.

The second request is nearly identical to one that was sent to CMS-Chicago, but that CMS apparently did not forward. So I am starting from scratch by sending you this one.

Thanks!

-- Jim O.

Exhibit
14

James T. O'Neill
235 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

December 1, 2005

VIA FACSIMILE TO 618-998-5287

Wisconsin Physicians Service (WPS)
Medicare Part B
Attn: Freedom Of Information Dept.
P.O. Box 4433
Marion, IL 62959

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that your agency provide the following agency records:

1. The "Advisory Committee Meeting Notes" related to Local Coverage Determinations Nos. L16830 through L16834. (Note: These LCDs themselves indicate that there are "Advisory Committee Notes" for meetings on 5/16/03 and 3/24/95 (Wisconsin); 5/28/2003 (Illinois); 5/7/03 (Michigan)' and 5/8/03 and 9/30/96 (Minnesota).). I think these LCDs all stem from Contractor's Determination PATH-016.

I agree in advance to pay fees of up to $250 without further consultation or approval. If your agency anticipates that charges will exceed $250, please contact me before exceeding this figure.

I will be happy to discuss with your agency possibly ways to reduce the scope and burden of the request. For example, LCDs L16830 through L16833 appear to be essentially the same document, with the sole difference between them being that they apply to different states. If there are four sets of records that are identical save for references to different states, there may be places where can cut down the paper involved by three-quarters.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

James T. O'Neill
325 West Huron Street
Suite 230
Chicago. Illinois 60610
(312) 654-8685

December 1, 2005

VIA FACSIMILE TO 618-998-5287

Wisconsin Physicians Service (WPS)
Medicare Part B
Attn: Freedom Of Information Dept.
P.O. Box 4433
Marion, IL 62959

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that your agency provide the following agency records:

1. All records concerning the adoption of Local Coverage Determinations L16830, L16831, L16832, and L16833 and (if it is something different or additional) Contractor's Determination Number PATH0016. (Note: These LCDs concern "Flow Cytometry.")

This request (without limiting its scope) includes the following, and references to L16830-33 are intended to include PATH-016:

(a) all comments received by your agency regarding any interim or final LCD for Flow Cytometry that preceded L16830-33;

(b) all records of communications between your agency and public commenters regarding the development of L16830-16833, including notes or other records of oral communications;

(c) all communications between WPS and CMS or IICFA regarding the consideration or adoption of L16830-16833; and

(d) all internal agency documents reflecting the considerations that led to the adoption of L16830-33.

I agree in advance to pay fees of up to $350 without further consultation or approval. If you anticipate that charges will exceed $350, please contact me before exceeding this figure.

Wisconsin Physicians Service (WPS)
Medicare Part B
December 1, 2005

I don't know exactly what kind of records your agency may maintain regarding the adoption of LCDs L16830-16833. For this reason, this request may be broader than it ultimately needs to be. I'm always happy to discuss with the agency possibly ways to reduce the scope and burden of the request.

For example, LCDs L16830 through L16833 appear to be essentially the same document, with the sole difference between them being that they apply to different states. If there are four sets of records that are identical save for references to different states, there may be places where can cut down the paper involved by three-quarters.

Finally, the last letter I received from WPS in response to a FOIA request did not contain information about whether and if so how I could take an administrative appeal of the response. If there are remedies you think I need to exhaust before seeking judicial review of your agency's response to this request, please let me know what they are in your response.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

Exhibit 15

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

P.O. Box 4433
Marion, IL 62959

January 3, 2006

James T. O'Neill
235 West Huron Street
Suite 230
Chicago, IL 60610

Refer to FOI #: 5509522042

Dear: Mr. O'Neill:

This is in response to your Freedom of Information Act (FOIA) request for advisory committee meeting notes and all records concerning the adoption of the Local Coverage Determinations on Flow Cytometry.

Records responsive to your request are not within our authority to release. Therefore, we have forwarded those records and a copy of your request to the official listed below. The cited individual will determine if the records may be disclosed to you.

Freedom of Information Group
Office of Strategic Operations and Regulatory Affairs, CMS
Room N2-20-16
7500 Security Boulevard
Baltimore, MD 21244
Attention: Melodye L Hardy
Phone: 410-786-5358

If you desire information regarding the status of your request, you may write or phone the above official.

Sincerely,

Freedom of Information

Government Contracts Division
Medicare Part B

CC: Melodye Hardy

Exhibit
15

Exhibit 16

(Blank – No Exhibit)

Exhibit 17

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

P.O. Box 4433
Marion, IL 62959

February 20, 2006

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, IL 60610

Dear Mr. O'Neill:

This is in response to your February 15, 2006, Freedom of Information Act (FOIA) request for all procedures, protocols, requirements or guidelines required to follow in responding to FOIA requests and procedures which members of the public must follow to take administrative appeals from denials of FOIA requests file with Medicare Part B carriers. Your request has been assigned FOIA Request No. 5609520189.

Records responsive to your request are not within our authority to release. Therefore, we have forwarded those records and a copy of your request to the official listed below. The cited individual will determine if the records may be disclosed to you.

Centers for Medicare and Medicaid Services, Region V
Attention: Susan Hahn Reizner, FOIA Coordinator
233 N. Michigan Ave;
Suite 600
Chicago, IL 60601

(312) 353-1504

If you desire information regarding the status of your request, you may write or phone the above official.

Sincerely,

Freedom of Information
Government Contracts Division
Medicare Part B

Exhibit
17

Exhibit 18

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

October 13, 2005

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. All records (including without limitation manuals, guidelines, guidance documents, letters, and circulars) that set forth CMS's policy of "first in, first out" FOIA case processing.

I agree in advance to pay fees of up to $350 without further consultation or approval. If CMS anticipates that charges will exceed $350, please contact me before exceeding this figure.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

Exhibit
18

Exhibit 19

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

Dec. 11, 2005

VIA FEDERAL EXPRESS

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. All records (including without limitation manuals, guidelines, guidance documents, letters, and circulars) that set forth CMS's policy of "first in, first out" FOIA case processing.

I agree in advance to pay fees of up to $350 without further consultation or approval. If CMS anticipates that charges will exceed $350, please contact me before exceeding this figure.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

P.S. This request is a duplicate of my request dated 10/13/05 that, according to the U.S. Postal Service, was delivered to CMS on 10/17/05. (USPS tracking number 0103 8555 7496 4020 0225.) I have received no CMS response to that request.

Exhibit 19

Exhibit 20

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations & Regulatory Affairs/Freedom of Information Group
Refer to: C06FOI0110(RIIR)

JAN 25 2006

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request of October 13, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

If you believe that your request should be expedited for any reason; i.e., such as a court date involving litigation, deadline for commenting on proposed regulations or other urgent matters, please notify us in writing and provide as much relevant information as possible. When submitting this additional information, please refer to the case number listed at the top left-hand corner of this letter, and send it to: Freedom of Information Group, N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

We are authorized by law to collect fees for responding to FOIA requests and assume that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250, we will send you an invoice for the full estimated costs and suspend further processing until payment of the invoiced amount is received. If estimated processing costs do not exceed $250, then we will send you an invoice for actual costs with our response.

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to: Rowena H. Rice (410) 786-5361

Exhibit
20

Exhibit 21

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

November 3, 2005

VIA FEDERAL EXPRESS

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. All documents delegating authority to CMS personnel to deny FOIA requests. (This request covers only documents that are currently in effect, i.e., it excludes delegations that been superseded.)

2. All documents delegating authority to CMS personnel to decide administrative appeals of FOIA denials. (This request covers only documents that are currently in effect, i.e., it excludes delegations that been superseded.)

I agree in advance to pay fees of up to $200 without further consultation or approval. If CMS anticipates that charges will exceed $200, please contact me before exceeding this figure.

Sincerely,

James T. O'Neill

Exhibit
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Exhibit 22

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850
Office of Strategic Operations and Regulatory Affairs/Freedom of Information Group

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refer to: C06FOI0247

NOV 22 2005

Mr. James T. O'Neill
325 West Huron Street, Suite 230
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request of November 3, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible and you will be notified of our decision regarding release or non-release of those documents.

If you believe that your request should be expedited for any reason; i.e., such as a court date involving litigation, deadline for commenting on proposed regulations or other urgent matters, please notify us in writing and provide as much relevant information as possible. When submitting this additional information, please refer to the case number listed at the top left-hand corner of this letter, and send it to: Freedom of Information Group, N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

We are authorized by law to collect fees for responding to FOIA requests and assume that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250, we will send you an invoice for the full estimated costs and suspend further processing until payment of the invoiced amount is received. If estimated processing costs do not exceed $250, then we will send you an invoice for actual costs with our response.

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE:
Any questions regarding the status of this request should be directed to: Jacqueline Russell 410-786-7427.

Exhibit
22

Exhibit 23

James T. O'Neill
325 West Huron Street
Suite 230
Chicago, Illinois 60610
(312) 654-8685

December 5, 2005

VIA FEDERAL EXPRESS

Freedom of Information Officer
Centers for Medicare & Medicaid Services
Freedom of Information Group
Room N2-20-16
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: FOIA Request

Dear Sir/Madam:

Pursuant to the Freedom of Information Act and applicable regulations, I request that CMS provide the following agency records:

1. All procedures, protocols, requirements, or guidelines that Medicare Part B carriers (such as Wisconsin Physicians Service Insurance Company) are required to follow in responding to FOIA requests.

2. All records reflecting procedures which members of the public must follow to take administrative appeals from denials of FOIA requests filed with Medicare Part B carriers, such as Wisconsin Physicians Service Insurance Company. In other words, if I file a FOIA request with WPSIC or another Medicare Part B carrier, and I am dissatisfied with the response, what agency records (if any) show an administrative remedy available to me?

I agree in advance to pay fees of up to $250 without further consultation or approval. If CMS anticipates that charges will exceed $250, please contact me before exceeding this figure.

Thank you in advance for your courtesy and cooperation, and for your commitment to open public records.

Sincerely,

James T. O'Neill

Exhibit
23

Exhibit 24

Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-20-16
Baltimore, Maryland 21244-1850
DEPARTMENT OF HEALTH & HUMAN SERVICES

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of Strategic Operations and Regulatory Affairs/Freedom of Information Group
Refer to: C06FOI0513 (JYF)

Mr. James T. O'Neill
325 West Huron Street, Suite 230
Chicago, Illinois 60610

Dear Mr. O'Neill:

I am acknowledging receipt of your Freedom of Information Act (FOIA) request dated December 5, 2005. Because we receive a very heavy volume of FOIA requests, we have had to establish a policy of "first in, first out" case processing. This policy is consistent with court decisions regarding FOIA's time limits. Please be assured that a search has been initiated for records falling within the scope of your request. If any such records are located, they will be reviewed as soon as possible, and you will be notified of our decision regarding release or non-release of those documents.

If you believe that your request should be expedited for any reason; i.e., such as a court date involving litigation, deadline for commenting on proposed regulations or other urgent matters, please notify us in writing and provide as much relevant information as possible. When submitting this additional information, please refer to the case number listed at the top left-hand corner of this letter, and send it to: Freedom of Information Group, N2-20-16, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

We are authorized by law to collect fees for responding to FOIA requests and assume that you are willing to pay the fees we charge for processing this request. If at anytime the costs for processing your request are estimated to exceed $250, we will send you an invoice for the full estimated costs and suspend further processing until payment of the invoiced amount is received. If estimated processing costs do not exceed $250, then we will send you an invoice for actual costs with our response.

Sincerely yours,

Michael S. Marquis
Director
Freedom of Information Group

NOTE: Any questions regarding the status of this request should be directed to: Mrs. Jean Faulcon (410) 786-5356.

Exhibit
24

Exhibit 25

United States Department of Health Human Services

HHS Fiscal Year 2005
Freedom of Information Annual Report

I. **AGENCY: U.S. Department of Health and Human Services**

REPORT PREPARED BY: Robert Eckert

TITLE: Director, Freedom of Information/Privacy Acts Division, Office of the Assistant Secretary for Public Affairs, HHS.

ADDRESS: Room 645-F, 200 Independence Avenue, S.W., Washington, D.C. 20201

PHONE NUMBER: (202) 690-7453

ELECTRONIC ADDRESS FOR THIS REPORT ON THE WORLD WIDE WEB:
http://www.hhs.gov/foia/05anlrpt.html

**** Copies of the annual reports of a number of individual HHS Operating Divisions can be found by contacting the responsible component shown in Section II below, or by locating a FOIA link at the following websites:**

Administration on Aging (AOA): http://www.aoa.gov/
Agency for Healthcare Research and Quality (AHRQ): http://www.ahrq.gov
Centers for Disease Control and Prevention (CDC): http://www.cdc.gov
Centers for Medicare & Medicaid Services (CMS): http://www.cms.gov
Food and Drug Administration (FDA): http://www.fda.gov
Health Resources and Services Administration (HRSA): http://www.hrsa.gov/
Indian Health Service (IHS): http://www.ihs.gov
National Institute of Health (NIH): http://www.nih.gov/
Office of Public Health and Science (OPHS): www.psc.gov/aos/foia/

ADDRESS FOR PAPER COPIES OF THIS REPORT:

Freedom of Information/Privacy Acts Division
U.S. Department of Health and Human Services
Hubert H. Humphrey Building/Room 645-F
200 Independence Avenue, S.W.
Washington, DC 20201

Exhibit 25

II. HOW TO MAKE A FOIA REQUEST: Please see HHS Guide to Information

Resources at www.hhs.gov/about/infoguid.html#foia

A. Names, addresses, and telephone numbers of all individual agency components and offices that process FOIA requests:

HHS Freedom of Information Officer
Room 645-F, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Telephone: (202) 690-7453

Administration for Children and Families (ACF)
Freedom of Information Officer
901 D Street, S.W.
Washington, D.C. 20447
Telephone: (202) 401-5967

Administration on Aging (AOA)
Freedom of Information Officer
Executive Secretariat
Washington D.C. 20201
Telephone: (202) 357-3540

Agency for Healthcare Research and Quality (AHRQ)
Freedom of Information Officer
540 Gaither Road, Room 2222
Rockville, MD 20850
Telephone: (301) 427-1866

Centers for Disease Control and Prevention (CDC) and/or
Agency for Toxic Substances and Disease Registry (ATSDR)
Freedom of Information Officer
1600 Clifton Rd, N.E., MSD 54
Atlanta, Georgia 30333
Telephone: (404) 639-7270

Centers for Medicare & Medicaid Services (CMS)
Freedom of Information Officer
7500 Security Boulevard
Room N2-20-16, North Building
Baltimore, Maryland 21244
Telephone (410) 786-5352

Food and Drug Administration (FDA)
Freedom of Information Officer
5600 Fishers Lane (HFI-35), Room 6-30
Rockville MD 20857
Telephone: (301) 827-6500

Health Resources and Services Administration (HRSA)
Freedom of Information Officer
Office of Communications, Room 14-23
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-2865

Indian Health Service (IHS)
Freedom of Information Officer
Suite 450
12300 Twinbrook Parkway,
Rockville, MD 20852
Telephone: (301) 443-1116

National Institutes of Health (NIH)
Freedom of Information Officer
Room 5B35, Building 31
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-5633

Office of Public Health and Science (OPHS)
Freedom of Information Officer, Room 17A-46
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-5252

Substance Abuse and Mental Health Services Administration (SAMHSA)
Freedom of Information Officer
Room 8-1042
1 Choke Cherry Road
Rockville, MD 20857
Telephone: (240) 276-2130

B. . Brief description of agency=s response time range(s): There is no overall time range because individual operating divisions (OPDIVS) have authority to release or deny their own records, and vary greatly in terms of the size and volume of FOIA requests processed. Individual OPDIV response times can range from same day response to over a year, depending on the complexity of the request.

C. Brief description of why some requests are not granted: Documents requested were protected by an exemption and release would have caused harm to the interest protected by the exemption.

III. DEFINITIONS OF TERMS AND ACRONYMS USED IN REPORT:

A. Agency-specific acronyms or other terms:

HHS - U.S. Department of Health and Human Services
OPDIVs - Operating Divisions of HHS
OS - Office of the Secretary, HHS
OASPA - Office of the Assistant Secretary for Public Affairs, HHS
AoA - Administration on Aging
ACF - Administration for Children and Families

AHRQ - Agency for Healthcare Research and Quality
ATSDR - Agency for Toxic Substances and Disease Registry
CDC - Centers for Disease Control and Prevention
FDA - Food and Drug Administration
HRSA - Health Resources and Services Administration
IHS - Indian Health Services
NIH - National Institutes of Health
OPHS - Office of Public Health and Science
PHS - Public Health Service
PRO - Professional Review Organization
PSC - Program Support Center
SAMHSA - Substance Abuse and Mental Health Services Administration

B. Basic terms (from FOIA UPDATE, Summer 1997):

FOIA/PA request - Freedom of Information/Privacy Act request. A FOIA request is generally a request for access to records concerning a third party, an organization, or a particular topic of interest. A Privacy Act request is a request for records concerning oneself. Such requests are also treated as FOIA requests. (All requests for access to records, regardless of which law is cited by the requester, are included in this report).

Initial Request - A request to a federal agency for access to records under the Freedom of Information Act.

Appeal - A request to a federal agency asking that it review at a higher administrative level a full denial or partial denial of access to records under the Freedom of Information Act, or any other FOIA determination such as a matter pertaining to fees.

Processed Request or Appeal - A request or appeal for which an agency has taken final action on the request or appeal in all respects.

Multi-track processing - A system in which simple requests requiring relatively minimal review are placed in one processing track and more voluminous and complex requests are placed in one or more other tracks. Requests in each track are processed on a first-in/first-out basis. A requester who has an urgent need for records may request expedited processing (see below).

Expedited processing - An agency will process a FOIA request on an expedited basis when a requester has shown an exceptional need or urgency for the records which warrants prioritization of his or her request over other requests that were made earlier.

Simple request - A FOIA request that an agency using multi-track processing places in its fastest (non-expedited) track based on the volume and/or simplicity of the records requested.

Complex request - A FOIA request, which an agency using multi-track processing places in a slower track, based on the volume and/or complexity of records requested.

Grant - An agency decision to disclose all records in full response to a FOIA request.

Partial grant - An agency decision to disclose a record in part in response to a FOIA request, deleting information determined to be exempt under one or more of the FOIA exemptions; or a decision to disclose some records in their entireties, but to withhold others in whole or in part.

Partial grant - An agency decision to disclose a record in part in response to a FOIA request, deleting

information determined to be exempt under one or more of the FOIA exemptions; or a decision to disclose some records in their entireties, but to withhold others in whole or in part.

Time Limits - The time period in the Freedom of Information Act for an agency to respond to a FOIA request (ordinarily 20 working days from proper receipt of a perfected FOIA request).

Perfected request - A FOIA request for records which adequately describes the records sought, which has been received by the FOIA office of the agency component in possession of the records, and for which there is no remaining question about the payment of applicable fees.

Exemption 3 statute - A separate federal statute prohibiting the disclosure of a certain type of information and authorizing its withholding under FOIA subsection (b)(3).

Median number - The middle number, not the average. For example, of 3, 7, and 14, the median number is 7.

Average number - The number obtained by dividing the sum of a group of numbers by the quantity of numbers in the group. For example, of 3, 7, and 14, the average number is eight.

IV. EXEMPTION 3 STATUTES

A. List of Exemption 3 statutes relied on by the agency during report year: (**See chart**)

1. Brief description of type(s) of information withheld under each statute: (**See chart**)

2. Has a court upheld the use of each statute? If so, cite example: (**See chart**)

V. INITIAL FOIA/PA ACCESS REQUESTS (Include all requests, 3rd or 1st party): (See chart below)

A. Numbers of initial requests (line 1 + line 2 - line 3 = line 4):

1. Number of requests pending at close of preceding fiscal year: 23,545
2. Number of requests received during reporting fiscal year: 222,372
3. Number of requests processed during reporting fiscal year: 221,402 (Includes 111 requests closed retroactively by NIH for FY 2004, for which disposition information is not available)
4. Number of requests pending at close of reporting fiscal year: 24,515 (This number should match Line VII.B.1.)

B. Disposition of Initial Requests: (See chart)

1. Number granted in full: 203,367
2. Number granted in part: 1,051
3. Number of full denials: 2,330

a. Number of times each FOIA exemption was used: (See chart)

Exemption 1: 0,000
Exemption 2: 53
Exemption 3: 49
Exemption 4: 570
Exemption 5: 215
Exemption 6: 2,846
Exemption 7

Exemption 7(A): 74
Exemption 7(B): 0
Exemption 7 (C): 21
Exemption 7 (D): 3
Exemption 7 (E): 1
Exemption 7 (F): 0

Exemption 8: 0000
Exemption 9: 0000

4. Other reasons for non-disclosure (total): 14,535 (See chart)

a. No records: 4,706
b. Referrals: 1.602
c. Request withdrawn: 2,859
d. Fee-related reason: 1,114
e. Records not reasonably described: 2,428
f. Not a proper FOIA request for some other reason:966
g. Not an agency record: 30
h. Duplicate request: 296
i. Other (specify): 1,074 (administrative closures--primarlly when requester did not respond to queries as to continued interest; and, when materials are more readily available from other sources, e.g. internet, libraries, etc.)

VI. **APPEALS OF INITIAL DENIALS OF FOIA/PA REQUESTS** (include all access requests whether first or third party, See chart):

A. Numbers of Appeals:

1. Number of appeals received during the fiscal year: 233
2. Number of appeals processed during the fiscal year: 164

B. Disposition of Appeals:

1. Number completely upheld: 40
2. Number partially reversed: 17
3. Number completely reversed: 35
   a. Number of times each FOIA exemption used (counting each exemption used once per appeal)

Exemption 1: 0
Exemption 2: 4
Exemption 3: 2
Exemption 4: 18
Exemption 5: 20
Exemption 6: 25
Exemption 7

Exemption 7(A): 1
Exemption 7(B): 0
Exemption 7(C): 2
Exemption 7(D): 1
Exemption 7(E): 0
Exemption 7(F): 0

Exemption 8: 0
Exemption 9: 0

4. Other reasons for non-disclosure (total): 72 (See chart)

a. No records: 19
b. Referrals:2
c. Request withdrawn: 22
d. Fee-related reason : 7
e. Records not reasonably described: 0
f. Not a proper FOIA request for some other reason: 0
g. Not an agency record: 0
h. Duplicate request: 0
I. Other (specify): 22 (administrative closures, material more readily available from other sources, e.g., internet,)libraries, etc.

VII. **COMPLIANCE WITH TIME LIMITS/STATUS OF PENDING REQUESTS:** (See chart)

A. Median Processing Time for Requests Processed During the Year: (Some OPDIVs do not use multiple tracks-see attached)

1. Simple Requests (if multiple tracks used):

a. number of requests processed: 49,301 (See chart)

b. median number of days to process: (See chart)

2. Complex Requests (includes total of complex requests and single-track systems):

a. number of requests processed: 172,044 (See chart)

b. median number of days to process: (See chart)

3. Requests Accorded Expedited Processing:

a. number of requests processed: 57

b. median number of days to process: (See chart)

B. Status of Pending Requests (if multiple tracks are being used, report for each track as well as totals). (See chart)

1. Number of requests pending as of the end of the fiscal year covered in this report (from Line V.A.4): 24,515

2. Median number of days that such requests were pending as of that date: Medians vary greatly from OPDIV to OPDIV. (See chart)

VIII. **COMPARISONS WITH PREVIOUS YEAR(S)**: (Optional):

A. Comparison of numbers of requests received: Decreased by 01.2%, from 225,006 to 222,372.

B. Comparison of numbers of requests processed: Decreased by 00.5%, from 222,408 to 221,402

C. Comparison of median numbers of days requests were pending as of end of fiscal year: See chart for Section VII

D. Other statistics significant to components: The HHS received 191 requests for expedited processing, of which 57 were granted.

The HHS is highly diversified; a number of OPDIVs experienced an increase in the number of FOIA requests received, while the IHS experienced a decline of 6,845 requests due primarily to a decrease in the number of medical records requests. The overall number of HHS FOIA requests that were processed decreased slightly.

The ACF, which previously had been serviced by the Office of the Secretary (OS) FOIA/PA office, established its own FOIA office in April 2005 to coordinate and respond directly to FOIA requesters. Each HHS OPDIV now has its own operating FOIA office to respond to most FOIA requesters directly.

E. Other narrative statements describing agency efforts to improve timeliness of FOIA performance and to make records available to the public (e.g., backlog-reduction activities; public availability of new categories of records): None.

IX. **COSTS/FOIA STAFFING**: (See chart)

A. Staffing levels:

1. Number of full-time FOIA personnel: 181

2. Number of personnel with part-time or occasional FOIA duties (in total work-years): 65.58

3. Total number of personnel (in work years): 246.58

B. Total costs (including staff and all resources):

1. FOIA processing (including appeals): $18,137,650

2. Litigation-related activities (estimated): $739,929

3. Total costs: $18,877,579

4. Comparison with previous year(s) (including percentage of change) (optional):

X. **FEES**: (See chart below)

A. Total amount of fees collected by agency for processing requests: $721,779

B. Percentage of total costs: 4%

XI. **FOIA REGULATIONS** (including fee schedule):

The FOIA regulation implementing the 1996 amendments to the Freedom of Information Act has been published as a Notice of Proposed Rule Making and public comments have been received. The passage of PL 105-277 requiring OMB to revise circular A-110 will require further revisions to the HHS FOIA regulation and public comments on those new sections. That effort is currently underway. Until such time as the revised regulation is published as a new final rule, the current HHS FOIA regulation can be found at 45 CFR Part 5, and at: www.hhs.gov/foia/45cfr5.html.

IV. Exemption 3 Statutes

Statute/Rule	Type of Information Withheld	Case Citation
5 U.S.C. 107(a)(2) Appendix 4	Confidential financial disclosure reports	Meyerhoff v. EPA, 958 F.2nd (9th Cir 1992)
35 U.S.C. 122	Information in a pending patent application	Irons and Sears v. Dann, 606 F.2d 1215 (D.C. Cir. 1979; Leeds v. Quigg, 720 F. Supp. 193 (D.C.C. 1989)
41 U.S.C. 253b (m)	Contractor proposals not incorporated into agency contracts	Hornbostel v. United States Dep't of the Interior, 305 F. Suppp. 2d 21 (D.D.C. 2003)
42 U.S.C. 242m(d) 308 (d)	National Death Index, information regarding fatalities	No
42 U.S.C. 300hh-12 (c), Section 121(c)	Bioterrorism-related information	No
42 U.S.C. 11137(b)	Adverse reports of a physician's conduct or practice	No

V. Initial FOI/PA Access Requests

V.A. Numbers of Initial Requests

(1)	Number of Requests Pending as of End of Preceding Year	Number of Requests Received in Current Year	Number of Requests Processed in Current Year	Number of Requests Pending as of End of Current Year
OS (2)	523	1,163	935	751
ACF (2)	0	158	141	17
AOA	0	31	22	9
CMS	4,084	35,198	34,347	4,935
OASPH	287	616	790	113
AHRQ	11	89	94	6
CDC	196	1,161	1,136	221
FDA	16,671	19,233	18,535	17,369
HRSA	46	375	386	35
IHS	41	151,429	151,428	42
NIH	1,632	12,718	13,382 (3)	968
SAMHSA	54	201	206	49
PHS Total	**18,938**	**185,822**	**185,957**	**18,803**
HHS Total	**23,545**	**222,372**	**221,402 (3)**	**24,515**

(1) Includes Privacy Act records requests
(2) The ACF, heretofore served by OS as its FOIA office, opened and initiated processing of FOIA requests in April 2005 for ACF records
(3) Includes 111 "pending" requests closed retroactively for FY 2004, for which disposition figures are unavailable.

V.B. Disposition of Initial Requests

	Number of Total Grants	Number of Partial Grants	Number of Full Denials	Total of Other Reasons for Nondisclosure
OS	250	303	28	354
ACF	31	80	0	30
AOA	4	7	1	10
CMS	23,322	94	2,160	8,771
OASPH	496	43	36	215
AHRQ	78	6	0	10

CDC	526	211	13	386
FDA	14,235	39	37	4,224
HRSA	291	15	18	62
IHS	151,329	61	21	17
NIH (1)	12,775	35	13 (1)	448
SAMHSA	30	165	3	8
PHS Total	**179,760**	**575**	**141 (1)**	**5,370**
HHS Total	**203,367**	**1,059**	**2,330 (1)**	**14,535**

(1) The NIH, and therefore the "total", disposition figures do not include 111 additional requests that were initially received in previous years and closed, for which disposition information is unavailable.

V.B.3. Exemptions Claimed Under the FOIA (1)

	(2)	(3)	(4)	(5)	(6)	(7) (A)	(7) (B)	(7) (C)	(7) (D)	(7) (E)	(7) (F)
OS	3	3	160	55	266	42	0	5	0	0	0
ACF	0	0	63	10	77	0	0	0	0	0	0
AOA	0	0	7	0	1	0	0	0	0	0	0
CMS	2	3	14	25	2209	1	0	9	1	0	0
OASPH	18	12	20	25	37	6	0	2	0	0	0
AHRQ	0	5	6	1	1	0	0	0	0	0	0
CDC	20	7	92	48	102	0	0	0	0	0	0
FDA	4	5	44	8	17	20	0	5	2	1	0
HRSA	0	3	10	13	5	5	0	0	0	0	0
IHS	3	5	41	5	28	0	0	0	0	0	0
NIH	3	5	41	5	28	0	0	0	0	0	0
SAMHSA	0	1	72	20	75	0	0	0	0	0	0
PHS Total	**48**	**43**	**326**	**125**	**293**	**31**	**0**	**7**	**2**	**1**	**0**
HHS Total	**53**	**49**	**570**	**215**	**2846**	**74**	**0**	**21**	**3**	**1**	**0**

(1) No claims for exemption (1), (8), or (9).

V.B.4. Other Reasons for Nondisclosure (Total)

No Records	Referrals	Request Withdrawn	Fee-Related Reason	Records Not Reasonably Described	Not a Proper FOIA Request	Not an Agency Record	Duplicate Request	Other

						for Some Other Reason			
OS	85	193	52	6	1	3	2	8	4
ACF	7	8	12	0	0	1	0	2	0
AOA	10	0	0	0	0	0	0	0	0
CMS	2921	715	575	612	2405	771	0	12	760 (1)
OASPH	91	62	59	3	0	0	0	0	0
AHRQ	5	0	4	1	0	0	0	0	0
CDC	222	14	61	6	0	0	25	20	38
FDA	1109	35	1916	454	0	191	0	249	270 (1)
HRSA	38	11	10	1	0	0	1	1	0
IHS	4	0	8	2	0	0	1	0	2
NIH	209	24	161	28	22	0	1	3	0
SAMHSA	5	0	1	1	0	0	0	1	0
PHS Total	**1683**	**146**	**2220**	**496**	**22**	**191**	**28**	**274**	**310**
HHS Total	**4706**	**1062**	**2859**	**1114**	**2428**	**966**	**30**	**296**	**1074**

(1) Administrative closures, primarily when requester did not respond to queries as to continued interest in FOIA request; and, when materials are more readily available from other sources, e.g., the internet and libraries

VII. Compliance With Time Limits/Status of Pending Requests

A. Median Processing Time for Requests Processed During the Year

	OS	ACF	AOA	CMS	OASPH	AHRQ	CDC	FDA	HRSA	IHS	NIH	SAM-HSA
1. a. Number of Simple Requests (Where multiple tracks used)	0	0	0	33,583	179	0	0	15,539	0	0	0	0
b. Median Days to Process	0	0	0	10	10 (1)	0	0	26	0	0	0	0
2.a.	0	0	0	722	611	0	0	1,987	0	0	0	0

Number of Complex Requests (Where multiple tracks used)												
b. Median Days to Process	0	0	0	86	60	0	0	370	0	0	0	0
3. a. Number of Expedited Requests	1	4	0	42	0	0	2	2	6	0	0	0
b. Median Days to Process	60	41	0	158	0	0	52	100	14	0	0	0
4. a. Number of Single Track Requests	934	137	22	0	0	94	1134	1,007	380	151,428	13,382 (1)	206
b. Median Days to Process	69 (3)	40	5	0	0	34	36	86	20	32	173	45

(1) Calculated median day figure does not include median day information for 55 additional OAPHS requests referred to other organizations, for which data is unavailable
(2) Calculated median day figure does not include median day information for 111 NIH FOIA requests closed retroactively for which median day data is unavailable
(3) Based on estimate

B. Status of Pending Requests

	OS	ACF	AOA	CMS	OASPH	AHRQ	CDC	FDA	HRSA	IHS	NIH	SAMHSA
1. Number of Requests Pending	751	17	9	2226 (1)	113	6	221	17369	35	42	968	49
2. Number of Median Days of	189 (2)	65	188	11	60 (3)	8	130	261 (3)	9	32	166	65

Pending Requests as of Septem-ber 30, 2004

2709
(4)

507

1. Simple requests
2. Based on sample
3. Multi-track median figures unavailable
4. Complex requests

IX. Costs/FOIA Staffing, and

X. Fees

	Staffing Levels			Costs (Estimated)			Fees	
	Full-Time Staff	**Staff With Part-Time or Occasional FOIA Duties (In Total Work-years)**	**Staff (In Work-Years)**	**FOIA Processing**	**Litigation-Related Activities**	**Total Costs**	**Total Fees Collected**	**% of Costs**
OS	5	0.00	5.00	$ 443,800	$ 147,409	$ 591,209	$ 10,058	2
ACF	2	0.50	2.50	153,036	0	153,036	2,238	2
AOA	0	0.08	0.08	5,152	0	5,512	0	0
CMS	70	11.80	81.80	2,222,150	29,602	2,251,752	213,910	10
OAPHS	4	0.00	4.00	206,678	38,462	245,140	8,483	4
AHRQ	1	0.25	1.25	66,146	0	66,146	726	1
CDC	5	0.00	5.00	330,584	0	330,584	37,556	11
FDA	71	14.90	85.90	11,133,436	487,314	11,620,750	392,145	3
HRSA	2	0.50	2.50	112,400	1,300	113,700	4,140	4
IHS	2	13.00	15.00	492,534	0	492,534	4,069	1
NIH	18	24.55	42.55	2,894,460	35,842	2,930,302	43,614	2
SAMHSA	1	0.00	1.00	77,274	0	77,274	4,840	6

PHS Total	**104**	**53.20**	**157.20**	**$15,313,512**	**$562,918**	**$15,876,430**	**$495,573**	**3**
HHS Total	**181**	**65.58**	**246.58**	**$18,137,650**	**$739,929**	**$18,877,579**	**$721,779**	**4**

Last revised: April 4, 2006